US005492538A

United States Patent [19]

Johlin, Jr.

[11] Patent Number: 5,492,538

[45] Date of Patent: Feb. 20, 1996

[54] METHOD FOR TRANSFERRING THE EXIT SITE OF A CATHETER FROM THE MOUTH TO THE NOSE AND INSTRUMENTATION USEFUL THEREFOR

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[21] Appl. No.: 295,595

[22] Filed: Aug. 25, 1994

[51] Int. Cl.[6] A61M 25/00

[52] U.S. Cl. 604/264; 604/283; 600/12; 128/657; 128/899

[58] Field of Search 604/280, 283, 604/905, 264; 600/12; 128/899, 657

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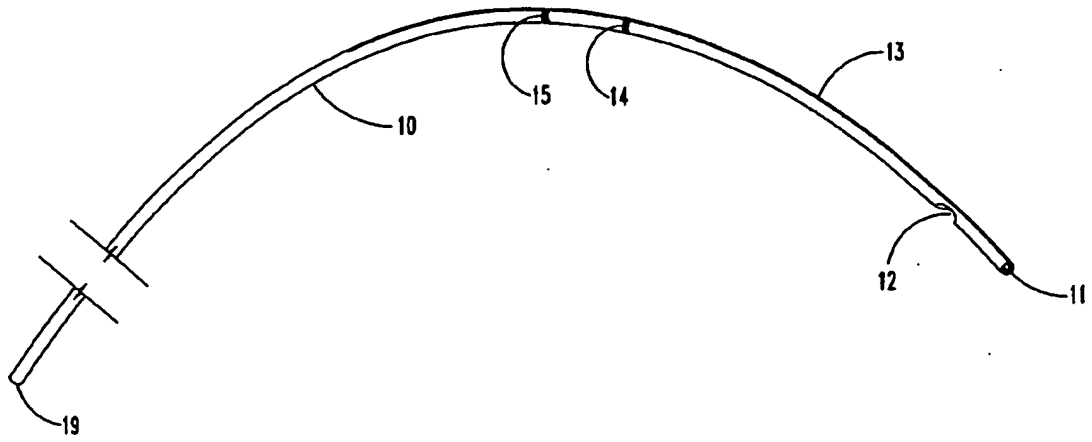
Primary Examiner—John D. Yasko

Attorney, Agent, or Firm—Woodward, Emhardt, Naughton, Moriarty & McNett

[57] ABSTRACT

A technique and instrumentation for transferring the exit site of a catheter, such as a nasal biliary catheter, from the mouth to the nose are described herein. The disclosed instrumentation includes a nasopharyngeal transfer catheter which has a tip of magnetically attractable material and a corresponding magnetic wand. The transfer catheter also includes a lateral hole therein near the its distal end which serves to facilitate attachment with the magnetic wand by increasing the flexibility of the transfer catheter in the direction towards the magnetic wand, while also providing access means for passing an nasal biliary catheter therethrough to effectuate the transfer of the nasal biliary catheter from the mouth to the nose. Alignment orientation and distance markings are also provided on nasalpharyngeal transfer catheter which facilitate the locating and attaching the tip of the transfer catheter to the magnetic wand.

3 Claims, 5 Drawing Sheets



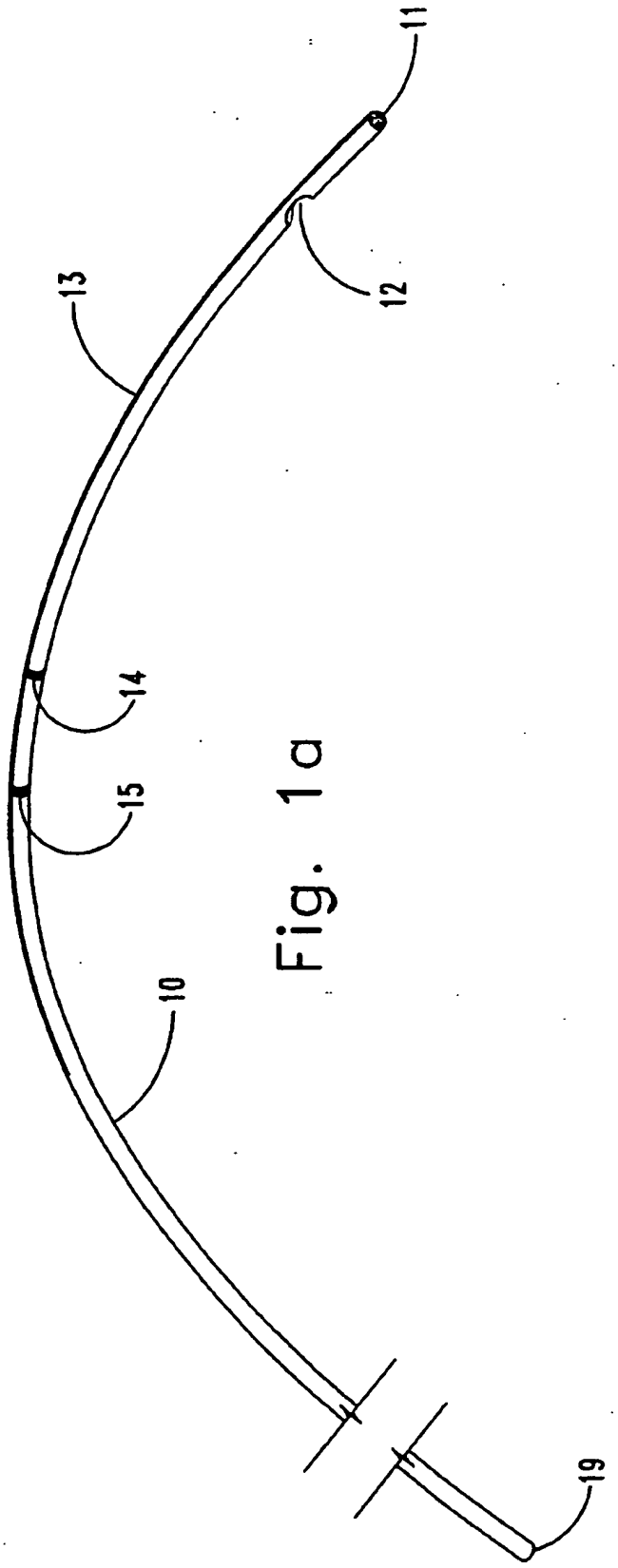


Fig. 1a

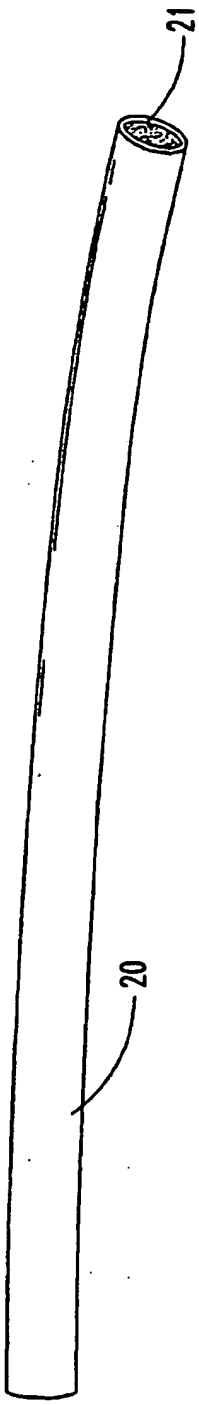


Fig. 1b

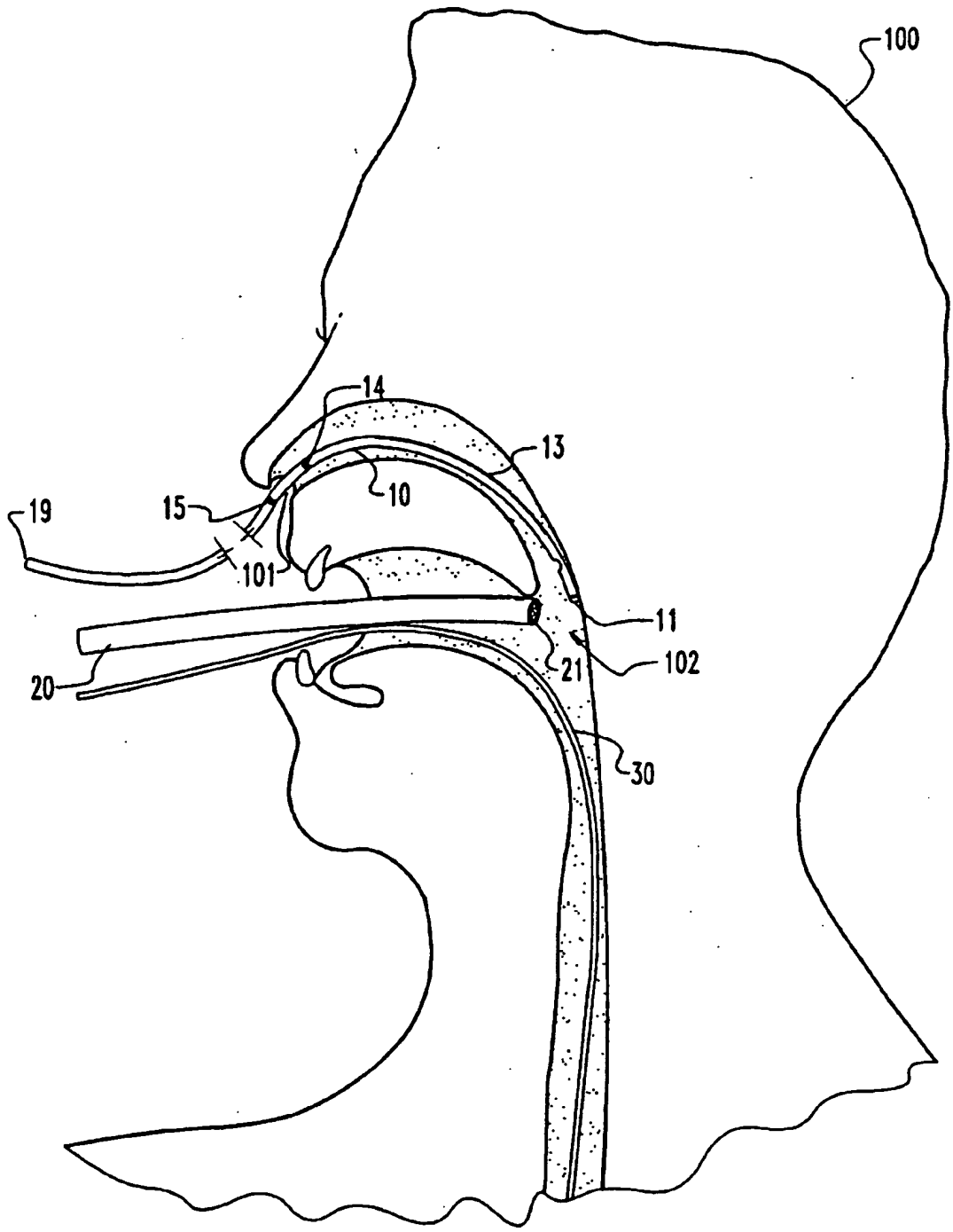


Fig. 2a

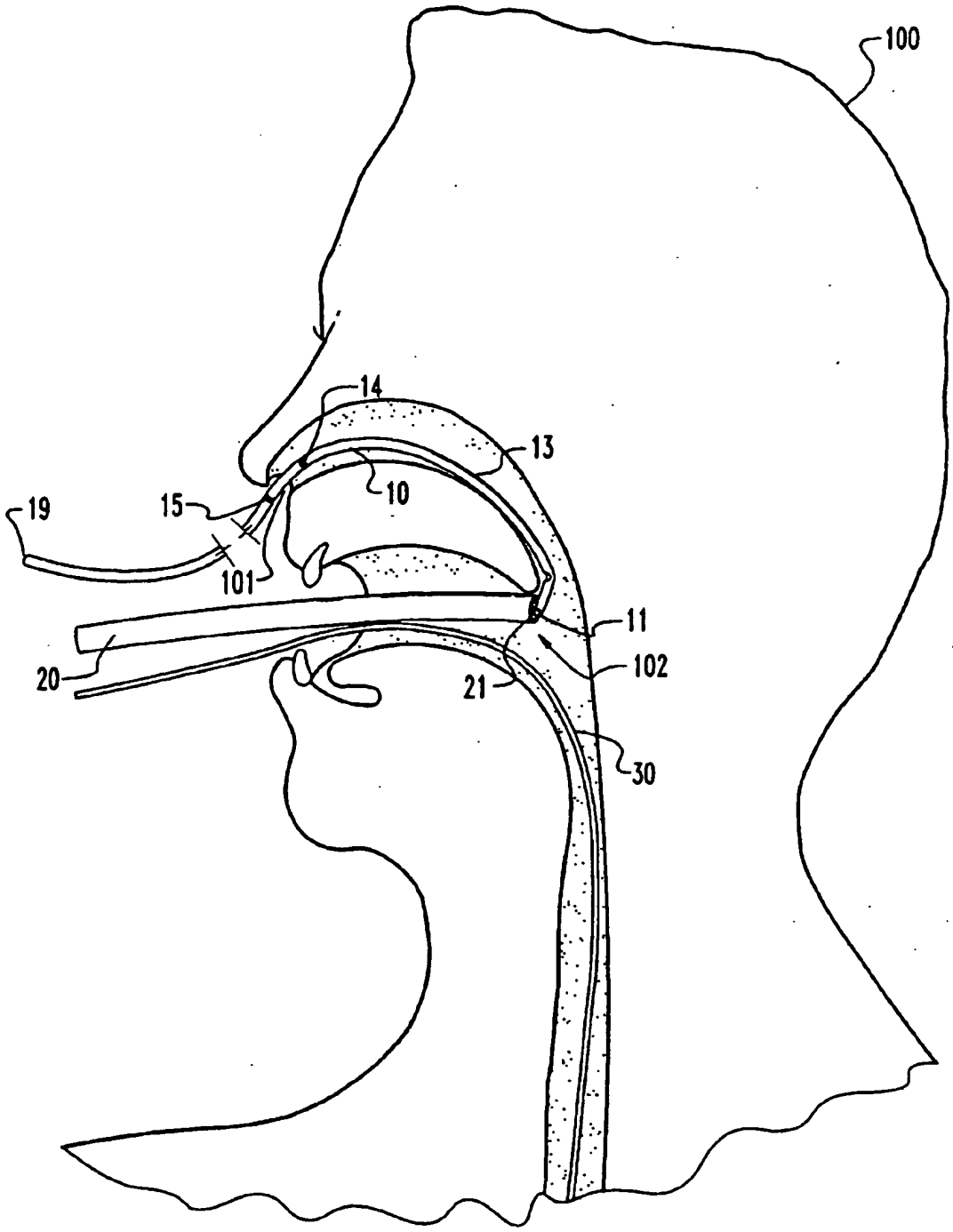


Fig. 2b

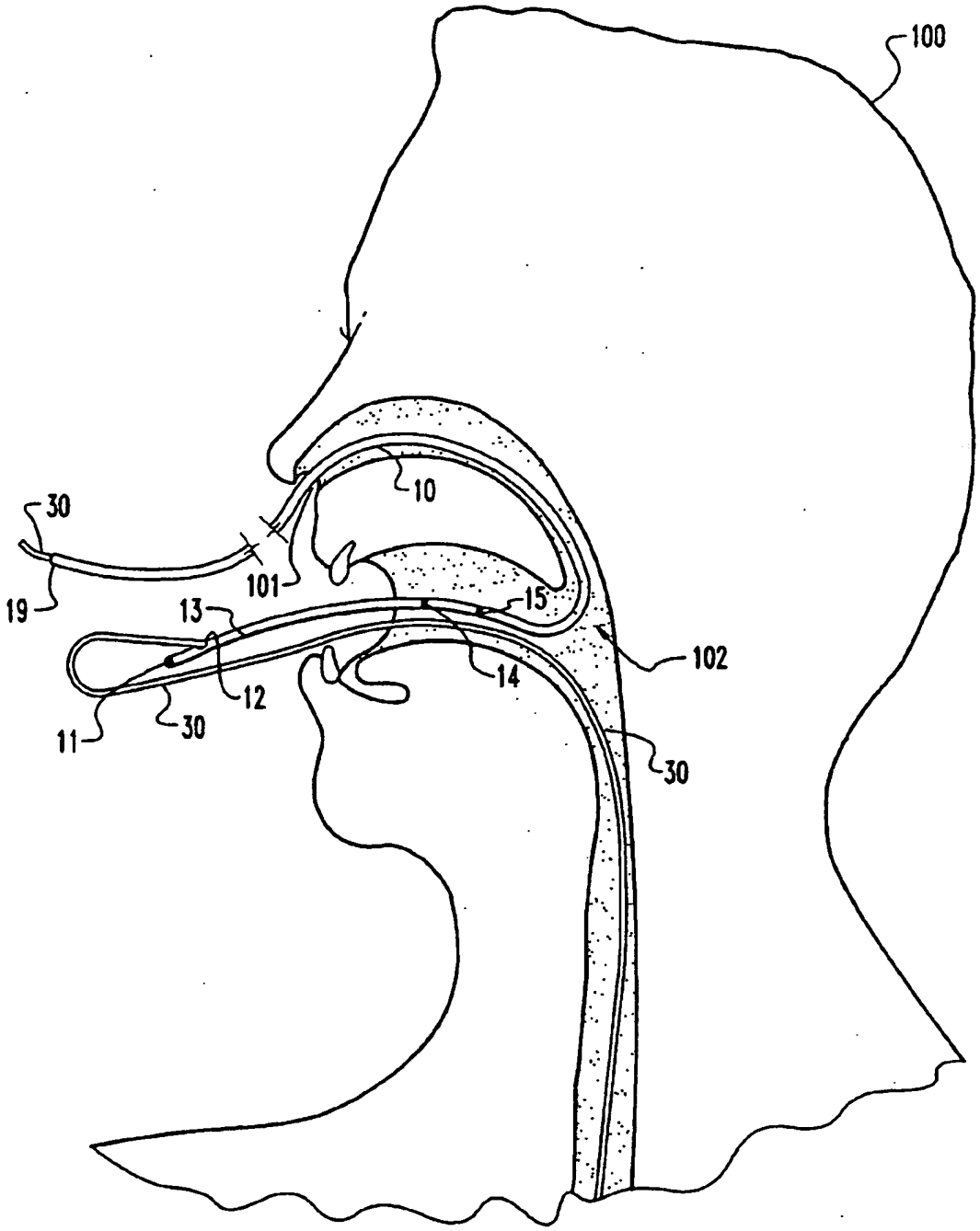


Fig. 2c

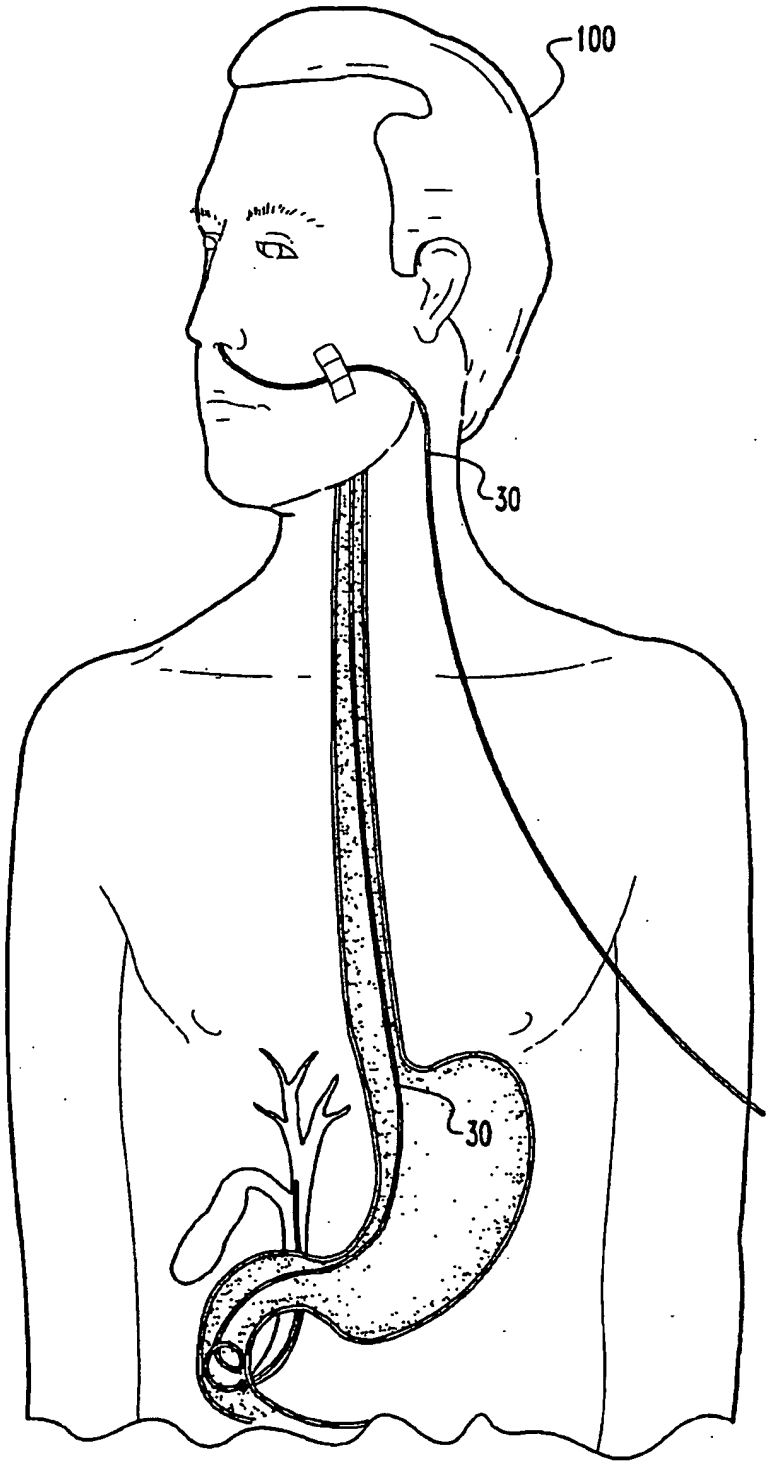


Fig. 3

METHOD FOR TRANSFERRING THE EXIT SITE OF A CATHETER FROM THE MOUTH TO THE NOSE AND INSTRUMENTATION USEFUL THEREFOR

BACKGROUND OF THE INVENTION

1. Field of the Invention

This invention relates to facilitating the transfer of the exit site of a catheter from the mouth to the nose. Devices that typically require this assistance include nasobiliary stents and endoscopically placed drainage and feeding devices. A device of the present invention could be useful in other procedures as well, such as, for example, the stabilization of nasally placed devices by a maneuver known as "bridling."

2. Description of the Prior Art

It is sometimes desirable to place a catheter into the biliary system, pancreas, or upper gastrointestinal tract through the mouth. After the catheter has been endoscopically implanted, the proximal end of the catheter is stationed out of the mouth of the patient. It is preferable, however, to transfer the exit site of the catheter to the nose, which is much more convenient and comfortable for the patient and reduces the risk that the catheter will be damaged by mastication. The transfer procedure is typically accomplished with the use of a well-lubricated nasopharyngeal tube which is advanced through the nostril and down the pharynx. The endoscopist then grasps the tip of the nasopharyngeal tube in the posterior oropharynx region with his or her index finger (or sometimes with forceps) and pulls it out through the mouth. The tip of the catheter is then threaded through a hole at or near the oral end of the nasopharyngeal tube and advanced until it exits through the nasal end of the tube. The nasopharyngeal tube is then slowly pulled out through the nostril, bringing the catheter along with it.

Problems are encountered in this procedure, however, in the process of locating, grasping, and pulling the nasopharyngeal tube out through the mouth once it has been advanced into the posterior oropharynx region. This is at least partly because the nasopharyngeal tube can sometimes be difficult to locate and grasp, particularly if the physician or assistant performing the maneuver has shorter fingers or the patient has an unusually small mouth. On occasion, the grasping digit has been bitten by the patient while trying to locate and pull the nasopharyngeal tube out through the mouth. The alternative of using a grasping instrument such as forceps, on the other hand, means that the posterior oropharynx region must be probed blindly to locate and securely grasp the nasopharyngeal tube for extraction. Without the benefit of a visual or tactile aid, a fair amount of time and effort is often required before the nasopharyngeal tube can be successfully extracted from the patient with forceps. And, as with the experience of having a hand reach into the back of your mouth, this blind probing with a foreign instrument into a sensitive region of the body can be uncomfortable and unpleasant for the patient and can result in trauma to the pharyngeal tissues. Both patient and physician would benefit from an improved way of accomplishing the transfer of a catheter from the mouth to the nose. Such an improved procedure would enable the physician to easily locate and extract the nasopharyngeal transfer device, and would do so in a way that would alleviate the unpleasantness and risks of the experience to the patient.

SUMMARY OF THE INVENTION

The present invention provides a new and safer way of transferring the proximal end of a catheter, such as a nasal biliary catheter, from the mouth to the nose, and provides new instrumentation which is designed for accomplishing this transfer. Such instrumentation, as described herein, enables the physician to be able to easily locate and extract a nasopharyngeal transfer catheter after it has been inserted into the nostril and through the nasal passageway and into the posterior oropharyngeal region. With the present invention, a physician can perform the procedure of transferring the exit site of a catheter from the mouth to the nose without risking injury from being bitten, and while also removing much of the unpleasantness and risk of the experience to the patient.

As described herein, instrumentation for the present invention includes a specially constructed nasopharyngeal transfer catheter with a tip of magnetically attractable material and a corresponding magnetic wand. A lateral hole which is formed near the distal end of the transfer catheter which both serves to facilitate attachment and provides access for passing a catheter therethrough as part of the transfer procedure. Orientation and distance markings are also provided which facilitate the locating and attaching of the transfer catheter tip to the magnetic wand.

It is an object of the present invention to provide a safe and easy way to transfer the exit site of a catheter from the mouth to the nose, and to do so in a way which is less traumatic for the patient. A full appreciation of this invention and its benefits can be drawn from a review of the following detail specification and claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1*a*** is a partially fragmented side elevational view of a nasopharyngeal transfer catheter which is specially constructed for use with the present invention. FIG. **1*b*** is a side elevational view of a magnetic wand which is used with the present invention to locate and extract the nasopharyngeal transfer catheter of FIG. **1*a*** out through the mouth after the transfer catheter has been passed in the nose and through the sinus passageways into the posterior oropharynx region.

FIGS. **2*a–c*** are side cross-sectional views of the head and neck portion of a patient **100**, and illustrating the nasal-oral-pharyngeal passageways therein and showing a nasal biliary catheter **30** which has been endoscopically placed into the patient. In FIG. **2*a***, nasopharyngeal transfer catheter **10** has been passed through the nasal passageways of the patient and in the posterior oralpharyngeal region, and magnetic wand **20** has been inserted through the mouth toward this region. FIG. **2*b*** shows transfer catheter **10** having been magnetically attracted towards wand **20** to form an attachment therewith. In FIG. **2*c***, transfer catheter **20** has been pulled out through the mouth by magnetic wand **20**, and nasal biliary catheter **30** has been advanced through lateral slot **12** and out through the proximal end **19** of nasopharyngeal transfer catheter **10**.

FIG. **3** is an illustration of patient **100** with the transfer procedure having been completed and with nasal biliary catheter **30** in fully in place for use.

DESCRIPTION OF THE PREFERRED EMBODIMENT

For the purposes of promoting an understanding of the principles of the invention, reference will now be made to the embodiment illustrated in the drawings and specific language will be used to describe the same. It will nevertheless be understood that no limitation of the scope of the invention is thereby intended, such alterations and further

modifications in the illustrated device, and such further applications of the principles of the invention as illustrated therein being contemplated as would normally occur to one skilled in the art to which the invention relates.

Referring now to the drawings, there is provided nasal transfer catheter **10** and magnetic wand **20** which are constructed to accomplish a secure attachment in the posterior oropharyngeal region with ease and with minimal resistance. For this purpose, wand **20** includes a high gauss magnet (for example, an alloy type magnet such as Alnico or reodynium-ion-boron) **21** at its distal tip and tip **11**, formed at the end of tubular transfer catheter **10**, is made of a suitably magnetized material that will attach to magnet **21**. Two distance markings **14** and **15** have been placed on transfer catheter **10** in the form of rings at 12 and 14 cm. distances, respectively, from distal tip **11** of transfer catheter **10**. Distance markings have been placed, in distance to distal tip **11**, to approximate the range of distances normally expected to be encountered in an adult patient between the nasolabial fold and his/her posterior pharynx.

Transfer catheter **10** additionally has an alignment orientation marking in the form of a long line **13** which is to be oriented cephalad, and transfer catheter **10** is also formed in a curvature along its length to facilitate advancement through the nasal passageway. When properly alligned with the aid of allignment orientation marking **13**, this curved structure allows transfer catheter **10** to easily follow the arc of the palate and pass into the posterior pharynx with less effort and trauma. Lateral hole **12**, which is disposed oppositely of orientation mark **13** on transfer catheter **10**, is oriented anteriorly to enhance the flexibility of transfer catheter **10** near its distal tip and to thus facilitate the forming of the desired attachment with magnetic wand **20**.

FIGS. **2***a–c* are side cross-sectional views of the head and neck portion of a patient **100**, and illustrating the nasal-oral-pharyngeal passageways therein and showing a nasal biliary catheter **30** which has been endoscopically placed into a patient. As shown in FIG. **2***a*, nasopharyngeal transfer catheter **10** has been advanced through the nasal passageways so that the first black ring **14** is no longer showing, and magnetic wand **20** has been introduced into the mouth of patient **100** and in toward the posterior oralpharyngeal region **102**. Preferably, magnetic wand **20** should be kept to one side and be positioned about 5 mm. away from the posterior pharynx.

If wand **20** does not engage transfer catheter **10** after wand **20** and transfer catheter **10** have been advanced as shown in FIG. **2***a*, the physician should then slowly advance transfer catheter **10** further until the second distance ring **15** is touching nasolabial fold **101**. Magnet **21** will then capture transfer catheter **10** in most adults. In children, the distance is more variable, thus requiring a visual estimation on the part of the physician. FIG. **2***b* shows transfer catheter **10** having been magnetically attracted towards wand **20** to form an attachment therewith. In FIG. **2***b*, it is also seen how lateral slot **12** enhances the flexibility of catheter **10** towards magnetic wand **20**, thereby facilitating the formation of the attachment.

In FIG. **2***c*, transfer catheter **10** has been pulled out through the mouth by magnetic wand **20**, and nasal biliary catheter **30** has been advanced through lateral slot **12** and out through the proximal end **19** of nasopharyngeal transfer catheter **10**. So configured, transfer catheter **10** and nasal biliary catheter **30** can be pulled out together through the nasal passageways and out through the nose to effectuate the desired transfer of nasal biliary catheter **30** to a nasal exit site.

It is preferred to use a high gauss force magnet **21** in magnetic wand **20** to ensure that catheter **10** is gripped with enough force to engage and drag catheter **10** out through the mouth. It is to be appreciated, though, that the invention may be practically performed with magnets of lesser strength. Also, a magnet could alternatively be placed on the distal tip of transfer catheter **10**, with magnetically attractive material placed on the distal tip of wand **20**, or two magnets, with oppositely disposed facing polarities, could be used as well.

While the invention has been illustrated and described in detail in the drawings and foregoing description, the same is to be considered as illustrative and not restrictive in character, it being understood that only the preferred embodiment has been shown and described and that all changes and modifications that come within the spirit of the invention are desired to be protected.

What is claimed is:

1. Instrumentation for transferring the proximal end of a catheter from the mouth to the nose, said instrumentation comprising:

a nasopharyngeal transfer catheter, said nasopharyngeal transfer catheter being generally tubular in structure and including a distal tip portion formed at least partially by magnetically attractable material, said transfer catheter being sized for insertion into a nostril of a patient and advanceable through the nasal passageway to position said distal tip portion of said transfer catheter in the posterior oralpharyngeal region; and

a wand, said wand including a distal tip portion formed at least partially by magnetically attractable material, said wand being sized for insertion into the mouth of a patient and advanceable therein to position said distal tip portion of said wand in the posterior oralpharyngeal region;

the magnetically attractable material in one of said distal tip portion of said transfer catheter and said distal tip portion of said wand being a magnet of sufficient strength to attract and attach to the magnetically attractable material in the other of said two distal tip portions when said two distal tip portions are both positioned in the posterior oralpharyngeal region, with the formed magnetic attachment being strong enough to enable said transfer catheter to be pulled out through the mouth by said wand.

2. The instrumentation of claim **1** in which said transfer catheter further has formed therein a lateral hole in proximity to said distal tip portion thereof providing access for passing a catheter through said transfer catheter while also enhancing the flexibility thereof at the distal tip portion of said transfer catheter in the direction of said lateral hole.

3. The instrumentation of claim **2** wherein said transfer catheter further includes an orientation marking along at least a portion of the length thereof to thereby provide a visual aid to facilitate the anterior allignment of said lateral hole when said transfer catheter has been advanced through the nasal passageway and into the posterior oralpharyngeal region.

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US005800497A

United States Patent [19]

Bakels et al.

[11] Patent Number: 5,800,497

[45] Date of Patent: Sep. 1, 1998

[54] MEDICAL ELECTRICAL LEAD WITH TEMPORARILY STIFF PORTION

[75] Inventors: Arnoldus P. Bakels, Simpelveld; Paul A. Gubbels, Brunssum; Nico M. Lokhoff, Kerkrade, all of Netherlands

[73] Assignee: Medtronic, Inc., Minneapolis, Minn.

[21] Appl. No.: 896,096

[22] Filed: Jul. 17, 1997

[51] Int. Cl.[6] A61N 1/05

[52] U.S. Cl. 607/122

[58] Field of Search 607/119, 122, 607/123, 120, 121; 600/377, 374, 373

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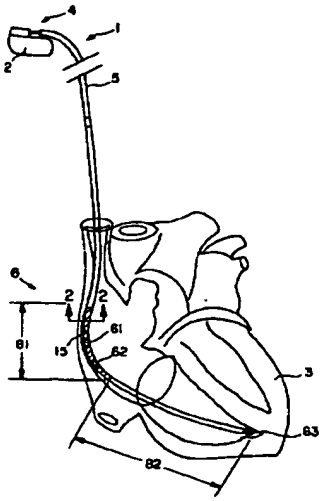
Primary Examiner—Scott M. Getzow

Attorney, Agent, or Firm—Michael J. Jaro; Harold Patton

[57] ABSTRACT

A medical electrical lead which features a portion of the lead body which may be made temporarily stiff. The lead preferred is designed for implantation into a body and would include electrodes for both the ventricle and the atrium. The temporarily stiff portion may be located along the lead body in the area strictly within the atrium or may also include portions of the lead body implanted in the ventricle or even in the superior vena cava. The atrial portion further includes one or more electrodes. The temporarily stiff portion is formed through the use of a cavity in the lead body filled with magnet-rheologic fluid (hereinafter called "MRF"). Once the lead is implanted, a magnet may be used to communicate with the lead body and, in particular, with the MRF filled cavity. While in the magnetic field, the MRF will become solid and the lead body in such an area will become stiffer. The lead body, moreover, in this area will also be attracted to the magnet thereby causing the lead body in that portion to migrate towards the magnet. The MRF filled cavity may either be cylindrical in cross-section or have other cross-sections, such as a semi-circle. The temporarily stiff portion may be located anywhere along the lead body between the proximal and distal ends. In the preferred embodiment the temporarily stiff portion is located between approximately 0 and 20 cm from the lead distal end and is between approximately 2 cm and 20 cm in total length. In an additional embodiment the lead is disclosed for coronary sinus placement. Finally, a further embodiment is shown which features MRF for the transfer of force from a stylet to the lead.

17 Claims, 4 Drawing Sheets



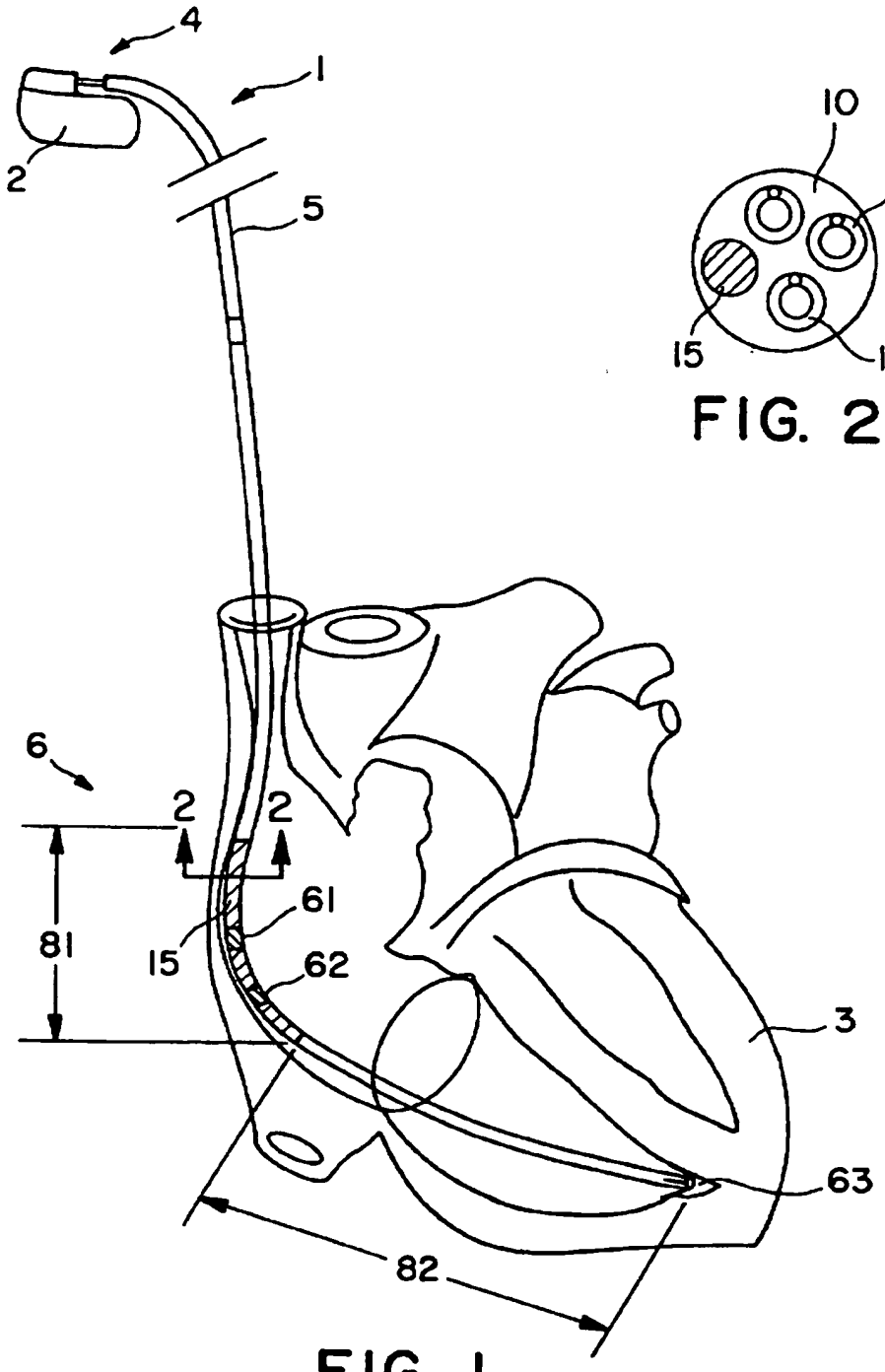


FIG. 1

FIG. 2

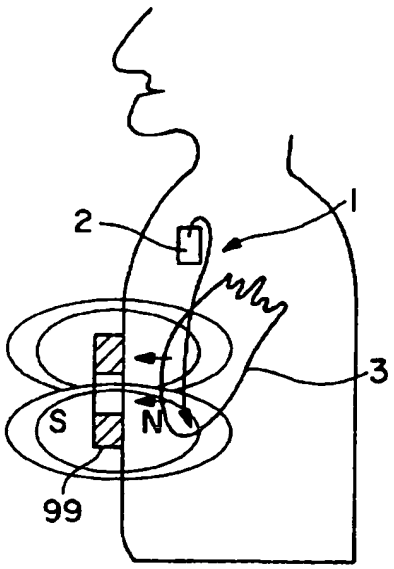


FIG. 3

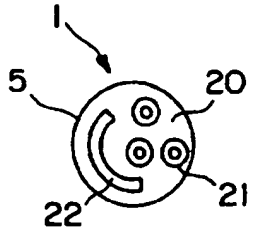


FIG. 4

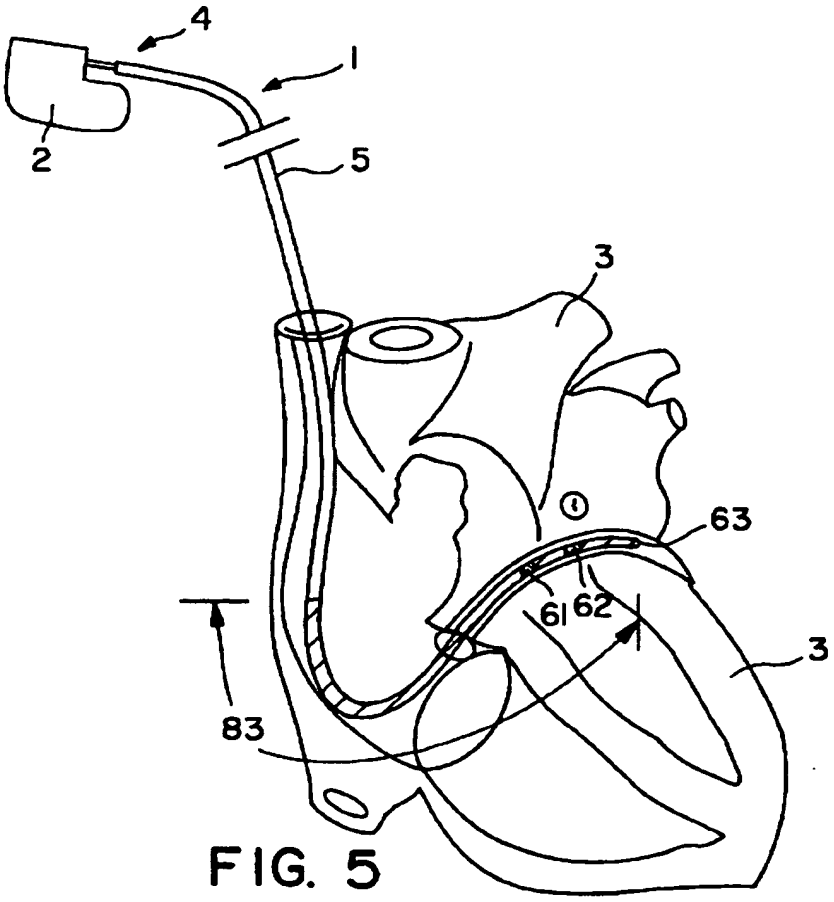


FIG. 5

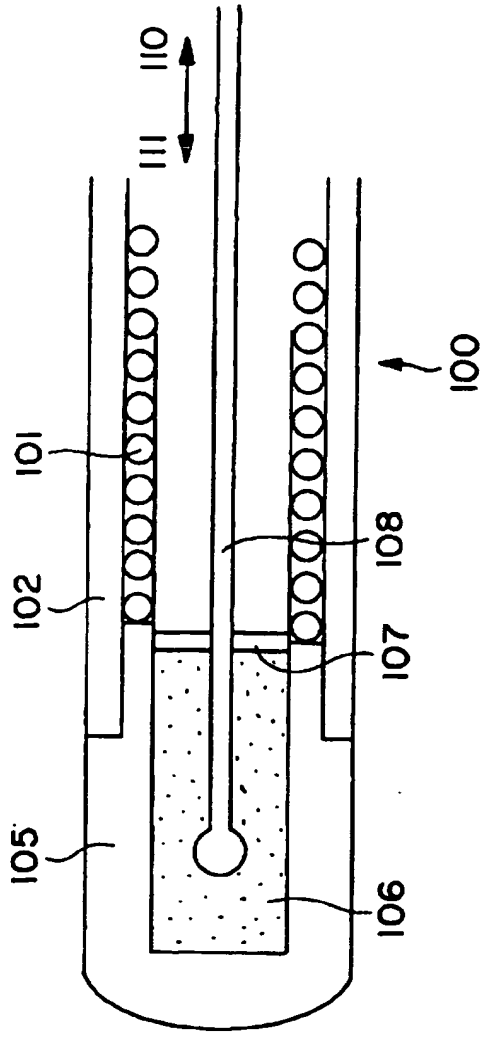


FIG. 6

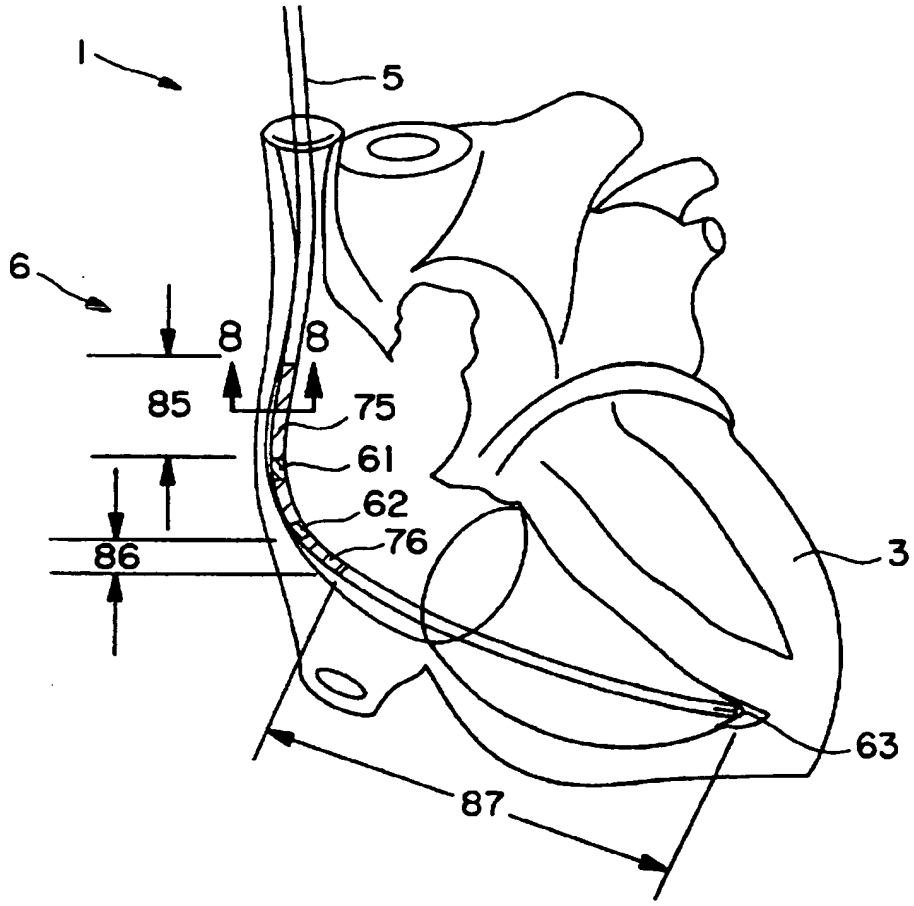


FIG. 7

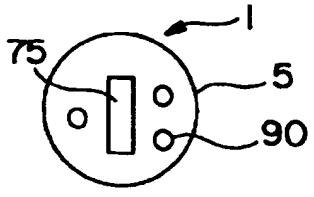


FIG. 8

MEDICAL ELECTRICAL LEAD WITH TEMPORARILY STIFF PORTION

FIELD OF INVENTION

The present invention relates to medical electrical leads and, more particularly, to medical electrical leads having a temporarily stiff portion.

BACKGROUND OF THE INVENTION

In the medical field, various types of body implantable leads are known and used. One type of commonly used implantable lead is an endocardial pacing lead.

Endocardial pacing leads are attached at their proximal end to an implantable pulse generator and at their distal end to the endocardium of a cardiac chamber. The distal end of an endocardial lead may engage the endocardium by either an active fixation mechanism or a passive fixation mechanism.

Active fixation mechanisms use a structure, such as helix or hook, to physically engage into or actively affix themselves onto the heart. Passive fixation mechanisms, such as a tine assembly, lodge or passively fix themselves to the heart.

One problem common to all such fixation systems, however, is to reliably fix such a lead in the atrial chamber. The atrium, unlike the ventricle, is relatively smooth in its interior. Thus, passive fixation systems, such as tines, are not able to reliably engage into structures along the interior portion of the atrium. The atrial chamber, moreover, is also generally thin. This means that there is not a large, meaty, portion of tissue available for an active fixation device to engage with.

Others have attempted to provide leads which may be adequately fixed into the atrium, these, however, have met with limited success. Gold, U.S. Pat. No. 4,454,888 provided a J-shaped atrial lead in which the pre-bent J-portion of the lead was formed using a separate metallic strip. During chronic use, however, this metallic strip often dislodged or separated from the lead body upon which it presented a sharpened metal barb to the tissues. Not surprisingly, this unfortunately had catastrophic consequences for the patients. Another approach to electrode placement within the atrium may be seen in the patent of Riestriena U.S. Pat. No. 4,401,126 which discloses a lead body having various loops and stiffness of the lead body in the atrium. This design, however, has several drawbacks, including it being difficult to implant and properly position the loop containing the electrodes, as well as the lead body being permanently stiff in the area of the atrium. Permanent stiffness of the lead body in the area of the atrium may have several drawbacks. First, because the lead is extra stiff in the area of the atrium and the atrium is not the most strong portion of the heart, the stiffened lead body may not permit the atrium to fully contract when such a lead is implanted. This can cause a hemodynamic insufficiency or impair cardiac output. Moreover, when a stiffened body is placed within the atrium the heart muscle may develop, in response to the object, so as to contract with greater force in the area. This increased area of heart tissue, often called cardiomyopathy, may have untoward effects on the conduction pathways, also contributing to diminished cardiac output.

SUMMARY OF THE INVENTION

The present invention concerns a medical electrical lead which features a portion of the lead body which may be made temporarily stiff. The lead preferred is designed for implantation into a body and would include electrodes for both the ventricle and the atrium. The temporarily stiff portion may be located along the lead body in the area strictly within the atrium or may also include portions of the lead body implanted in the ventricle or even in the superior vena cava. The atrial portion further includes one or more electrodes. The temporarily stiff portion is formed through the use of a cavity in the lead body filled with magnetrheologic fluid (hereinafter called "MRF"). Once the lead is implanted, a magnet may be used to communicate with the lead body and, in particular, with the MRF filled cavity. While in the magnetic field, the MRF will become solid and the lead body in such an area will become stiffer. The lead body, moreover, in this area will also be attracted to the magnet thereby causing the lead body in that portion to migrate towards the magnet. The MRF filled cavity may either be cylindrical in cross-section or have other cross-sections, such as a semi-circle. The temporarily stiff portion may be located anywhere along the lead body between the proximal and distal ends. In the preferred embodiment the temporarily stiff portion is located between approximately 0 and 20 cm from the lead distal end and is between approximately 2 cm and 20 cm in total length. In an additional embodiment the lead is disclosed for coronary sinus placement. Finally, a further embodiment is shown which features MRF for the transfer of force from a stylet to the lead.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a view of a system featuring a lead of the present invention.

FIG. 2 is a cross-sectional view of the lead body shown in FIG. 1.

FIG. 3 is a side view showing a lead implanted within a patient and a magnet used to stiffen the lead body.

FIG. 4 is a alternate embodiment of the lead shown in FIG. 1.

FIG. 5 is an alternate embodiment of a lead which is designed for implantation in the coronary sinus.

FIG. 6 is an alternative embodiment of a lead.

FIG. 7 is a alternate embodiment of the lead shown in FIG. 1.

FIG. 8 is a cross-sectional view of the lead body shown in FIG. 7.

The FIGS. are not necessarily to scale.

DETAILED DESCRIPTION OF THE DRAWINGS

It is to be understood, that the present invention is not limited to use only in introducing atrial or ventricular pacing leads, and may be employed in introducing many of various types of therapeutic or diagnostic devices including transvenous leads intended to be disposed at various places within patient, including, for example, leads intended to be disposed within the patient's coronary sinus, as well as various other types of electrical leads, including nerve, muscle or defibrillation leads. It is to be further understood, moreover, the present invention may be employed in introducing many of various types of therapeutic or diagnostic catheters and is not limited only to the introduction of electrical leads. For purposes of illustration only, however, the present invention is below described in the context of the introduction of endocardial pacing leads. The term "lead," however, is used in the broadest possible manner and should be read to include any elongated medical device.

FIG. 1 is a view of a lead of the present invention. As seen, lead 1 is used to couple an implantable pulse generator

2 to a heart 3. Implantable pulse generator as used herein refers to any device which provides electrical stimulation therapy to a body tissue or organ and is not intended to merely be limited to a so-called pacemaker. In the preferred embodiment, however, implantable pulse generator comprises any dual chamber model selected from the Medtronic Thera series of pacemakers. As seen, lead 1 has essentially three portions, a connector pin assembly 4, a lead body 5 and an electrode portion 6. Connector pin assembly 4 is of any standard design suitable for use of coupling the lead to an implantable medical device such as those connectors conforming to the IS-1 standard, to name an example. Lead body 5 is constructed from an insulative sheath 10 and one or more conductors 11, as best seen in FIG. 2. Electrode portion 6 of lead body features a pair of electrode 61, 62 spaced apart a distance 8.6 mm. Further details concerning atrial electrodes as well as the tip electrode 63 which may be used can be found in the U.S. Pat. No. 5,628,778 "Single Pass Medical Electrical Lead" of Kruse et al. assigned to the assignee of the present invention and incorporated herein by reference. As discussed in more detail below, the electrode portion of the lead body features one or more cavities containing MRF fluid. Thus, when the MRF is made solid through the presence of a magnetic field, the corresponding section of the lead body will become stiffer. As seen in this embodiment the MRF 15 extends for a length 81 at a distance 82 from the distal end of the lead. In the preferred embodiment both length and distance are approximately 8 cm. Of course, each dimension may vary, it is conceived the cavity containing MRF may extend for a length of approximately 2–20 cm at a distance from approximately 0–20 cm from the distal end of the lead. Moreover, although a single MRF cavity is illustrated, multiple cavities containing MRF may also be implemented, as shown below.

FIG. 2 is a cross-section of the lead body shown in FIG. 1. As mentioned above, lead body is constructed from an insulated polymer sheath 10 and one or more conductors 11. In the preferred embodiment sheath is silicone and has four cylindrical cavities running at least within a portion of the length of the sheath. Positioned along the length of three such cavities are the conductors. In the preferred embodiment conductors are coiled multi-filar conductors of a biocompatible alloy such as MP35N. Although shown as coiled conductors it should be understood other devices of conductors may also be used such as bundle stranded wires. Moreover, the coiled design of the conductors as well as their cross-sections may also be varied if desired. As seen, a fourth lumen within the sheath is filled with MRF 15. As discussed above, MRF is a material which normally exists in a liquid form, but, in the presence of a sufficiently intense magnetic field, will act as a solid. The particular intensity necessary to achieve the desired transformation of the MRF from liquid to solid depends upon the particular MRF used. In the preferred embodiment the MRF is model MRF 32 LD, a silicone oil based MRF available from Lord Corporation, 405 Gregson Drive, Cary, N.C., U.S.A.

FIG. 3 is a side view showing a lead according to the present invention implanted within a patient having a magnet placed in proximity to thereby cause the lead body to stiffen. As discussed above, the MRF solidifies when in the presence of a magnet 99. The lead according to the present invention features a portion of the lead body having MRF therein. When such a lead is placed in the presence of a magnetic field the MRF will solidify causing the lead body flex characteristics to thereby also solidify or stiffen. Through such a design, the lead body will be drawn against the heart wall in the direction shown thereby causing the electrodes to become in better contact with the heart tissue. Moreover, due to the increased stiffness of the lead body in this portion, the heart tissue will be aggravated by the temporarily stiff lead body thereby accelerating the growth of fibrotic tissue in this area. Ultimately, such fibrotic tissue growth will act to fix or couple, through such tissue, the lead body, and thus the nearby electrodes, to the heart. Long term, this means the lead is better coupled to the previously uncouplicable atrial tissue. In addition, the lead body in this area will also be attracted to the magnet thereby causing the lead body in that portion to migrate towards the magnet and further assist in the optimal contact of the electrodes to the heart tissue. Once sufficient fibrotic tissue growth is seen, then the magnetic field is removed and the lead body again goes into a relatively more flexible or flaccid disposition. The magnetic field may be provided using either a conventional magnet or some sort of electromagnet, whichever is preferred. As discussed above, the particular intensity necessary to achieve the desired transformation of the MRF from liquid to solid depends upon the particular MRF used. Moreover, because implantable pulse generators typically utilize magnetic reed switches it is further comprehended that a second magnet (not shown) may be provided in the vicinity of the pulse generator to prevent the lead body stiffened magnet to reset or trip reed switch in the pulse generator.

FIG. 4 is a alternative embodiment of the lead shown in FIG. 1. In particular, in this FIG. the lead shown in FIG. 1 is entirely the same but for a varied cross-section of the lead body. As seen in this embodiment, the lead body is an insulative sheath 20 having a series of three lumens 21 being circular in cross-section with a fourth lumen 22 being semi-circular in cross-section. Through such a cross section the flex characteristics of the lead body in the vicinity of the MRF may be changed, in particular, the lead body may be made to become more stiff due to the MRF as compared to a simple cylinder filled with MRF. Moreover, although the semi-cylindrical shape is shown, other shapes may be used, such as squares, ellipses, rectangles or any combination thereto.

FIG. 5 is an alternative embodiment of a lead design for implantation in the coronary sinus. As seen the lead body in this embodiment features an MRF portion which extends from the distal end of the lead for an amount preferably between 12–15 cm so that it extends, in a patient, from the SVC to the great vein. Through this design the distal portion of the lead body may be stiffened using a magnet to thereby increase the ease of insertion of the lead in the coronary sinus. In this embodiment the lead further features a distal type electrode as well as two ring electrodes of a design well known in the art.

FIG. 6 is an alternative embodiment of a lead. In this embodiment MRF is used so as to enhance the ability of a stylet to control the end of the lead without necessitating any complex stylet lead interlocks. As seen lead 100 is constructed in a typical fashion, featuring coiled conductor 101 and insulative sheath 102. Both sheath and conductor may be fabricated from any desired material, such as silicone and MP35N respectively to name an example. Positioned on the distal end of lead is distal cap assembly 105. Distal cap assembly feature a cavity filled with MRF 106. Distal cap assembly further features a valve 107 so as to maintain the MRF while in the fluid state within cavity. Valve may be of any design such that a stylet 108 may be introduced therethrough and into the MRF. In the embodiment shown valve comprises a annular flap of silicone having a hole therethrough. Stylet features a bulb at its distal end. Bulb

increases the amount of friction between the MRF and the stylet once the MRF is made solid. This permits the stylet to be pulled in the direction **110** or pushed in the direction **111** so as to better enable MRF and stylet to manipulate the lead. As described above, MRF is only solid within the presence of a sufficient magnetic field. Thus, once the magnet is removed, then stylet may be easily removed from MRF **106**. Although not illustrated, it is quite possible to make the stylet itself electromagnetic such that the stylet could be used to modify the state of the MRF.

FIG. **7** is an alternative embodiment of the present invention. In this FIG. only the distal half of lead **1** is shown, although connector pin assembly is the same as that discussed above. In this embodiment electrode portion **6** of lead body **5** feature a pair of cavities **75, 76** containing MRF fluid. Cavity **75** extends for a length **85** of between approximately 1–10 cm with approximately 4 cm preferred. Cavity **76** extends for a length **86** of between approximately 1–10 cm with approximately 4 cm preferred. As seen each cavity borders an electrode **61, 62** which function as a bipolar electrode for use in stimulating and sensing the heart. As discussed above, electrodes may be constructed in any suitable fashion known in the art. The electrodes are spaced apart a distance 8.6 mm. Further details concerning atrial electrodes which may be used can be found in the U.S. Pat. No. 5,628,778 "Single Pass Medical Electrical Lead" of Kruse et al. assigned to the assignee of the present invention and incorporated herein by reference.

FIG. **8** is a cross sectional view across line **8—8** of the lead body shown in FIG. **7** As seen in this embodiment the MRF containing cavity **75** is rectangular in cross section. Although only one cavity is shown in this view, the other cavity **76** is also rectangular in shape. In this embodiment the conductors **90** used are fashioned from HBSW wire of MP35N.

Although a specific embodiment of the invention has been disclosed, this is done for the purposes of illustration and is not intended to be limiting with regard to the scope of the invention. It is contemplated that various substitutions, alterations, and/or modifications, including but not limited to those specifically discussed herein, may be made to the disclosed embodiment of the invention without departing from the spirit and scope of the invention as defined in the appended claims, which follow.

What is claimed is:

1. A medical electrical lead comprising:

a lead body, the lead body having a first portion and a second portion, the lead body further having an insulative sheath and a conductor, the insulative sheath having a first end and a second end, the conductor positioned within the insulative sheath and extending between the first end and the second end;

means for temporarily making a first portion of the lead body more stiff by exposing the first portion to a magnetic field; and

an electrode positioned near the second end, the electrode coupled to the conductor.

2. A medical electrical lead according to claim **1** wherein the means for temporarily making a first portion of the lead body more stiff comprises a first cavity in the first portion of the lead body, the first cavity containing a first amount of MRF.

3. A medical electrical lead according to claim **2** wherein the first cavity is within the insulative sheath.

4. A medical electrical lead according to claim **2** wherein the first cavity comprises a cylindrical cavity.

5. A medical electrical lead according to claim **4** wherein the cylindrical cavity is within the insulative sheath.

6. A medical electrical lead according to claim **2** wherein the first cavity is located approximately 8 cm from the distal tip.

7. A medical electrical lead according to claim **2** wherein the first cavity is approximately 8 cm long.

8. A medical electrical lead comprising:

a lead body, the lead body having a first portion and a second portion, the lead body further having an insulative sheath and a conductor, the insulative sheath having a first end and a second end, the conductor positioned within the insulative sheath and extending between the first end and the second end;

a stylet positioned extending from a first end of the lead body into an interior portion of the lead body

means for temporarily permitting the longitudinal transfer of force between the stylet and the lead body by exposing the lead body to a magnetic field.

9. A medical electrical lead according to claim **8** wherein the lead body has at least a first cavity in the first portion, the first cavity containing a first amount of MRF.

10. A medical electrical lead comprising:

a lead body, the lead body having a first portion and a second portion, the lead body further having an insulative sheath and a conductor, the insulative sheath having a first end and a second end, the conductor positioned within the insulative sheath and extending between the first end and the second end;

means for temporarily making the first portion of the lead body more stiff by exposing the first portion to a first magnetic field;

means for temporarily making the second portion of the lead body more stiff by exposing the second portion to a second magnetic field; and

an electrode positioned near the second end, the electrode coupled to the conductor.

11. A medical electrical lead according to claim **10** wherein the means for temporarily making a first portion of the lead body more stiff comprises a first cavity in the first portion of the lead body, the first cavity containing a first amount of MRF.

12. A medical electrical lead according to claim **10** wherein the means for temporarily making a second portion of the lead body more stiff comprises a second cavity in the second portion of the lead body, the second cavity containing a first amount of MRF.

13. A medical electrical lead according to claim **12** wherein the first cavity is within the insulative sheath.

14. A medical electrical lead according to claim **12** wherein the first cavity comprises a cylindrical cavity.

15. A medical electrical lead according to claim **14** wherein the cylindrical cavity is within the insulative sheath.

16. A medical electrical lead according to claim **12** wherein the first cavity is located approximately 8 cm from the distal tip.

17. A medical electrical lead according to claim **12** wherein the first cavity is approximately 8 cm long.

* * * * *

US005843153A

United States Patent [19]

Johnston et al.

[11] Patent Number: 5,843,153

[45] Date of Patent: Dec. 1, 1998

[54] **STEERABLE ENDOCARDIAL LEAD USING MAGNETOSTRICTIVE MATERIAL AND A MAGNETIC FIELD**

[75] Inventors: **Matthew M. Johnston; Steven R. Conger**, both of Angleton, Tex.

[73] Assignee: **Sulzer Intermedics Inc.**, Angleton, Tex.

[21] Appl. No.: **893,279**

[22] Filed: **Jul. 15, 1997**

[51] **Int. Cl.**[6] **A61M 25/01**

[52] **U.S. Cl.** **607/122**; 600/585

[58] **Field of Search** 600/585; 607/122, 607/125

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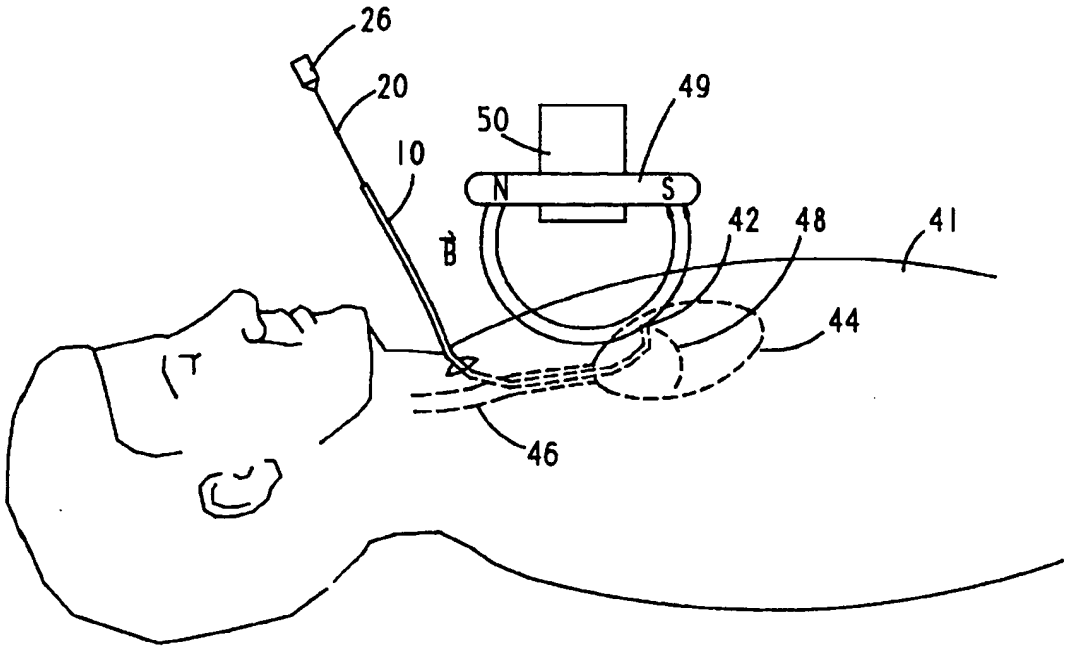
Primary Examiner—William E. Kamm
Assistant Examiner—Carl H. Layno
Attorney, Agent, or Firm—John R. Merkling

[57] **ABSTRACT**

Magnetically alterable material, such as magnetostrictive material, is used in combination with a suitable substrate and a suitable magnetic field to produce a stylet and lead assembly that curves in response to a suitable magnetic field.

15 Claims, 6 Drawing Sheets



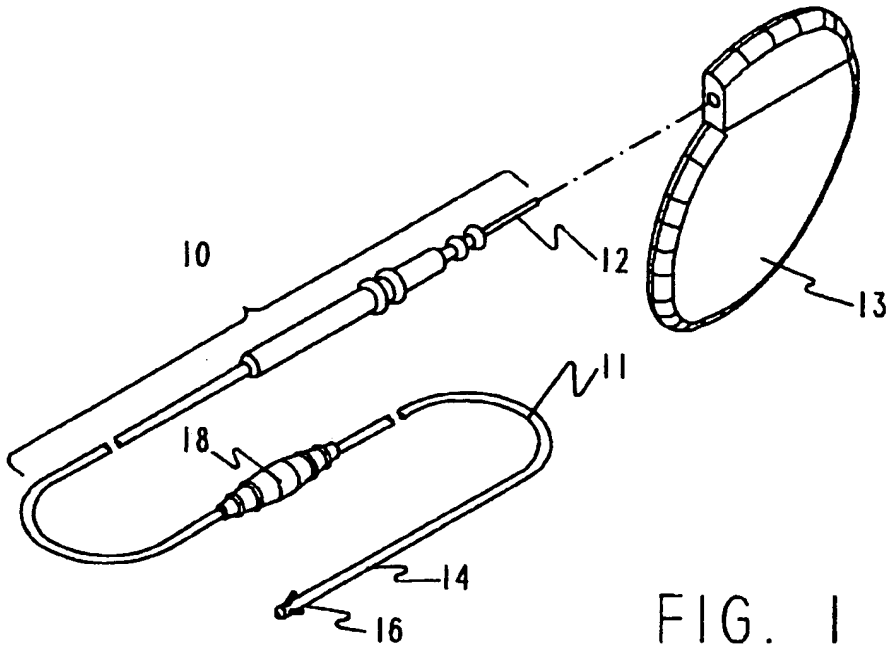


FIG. 1

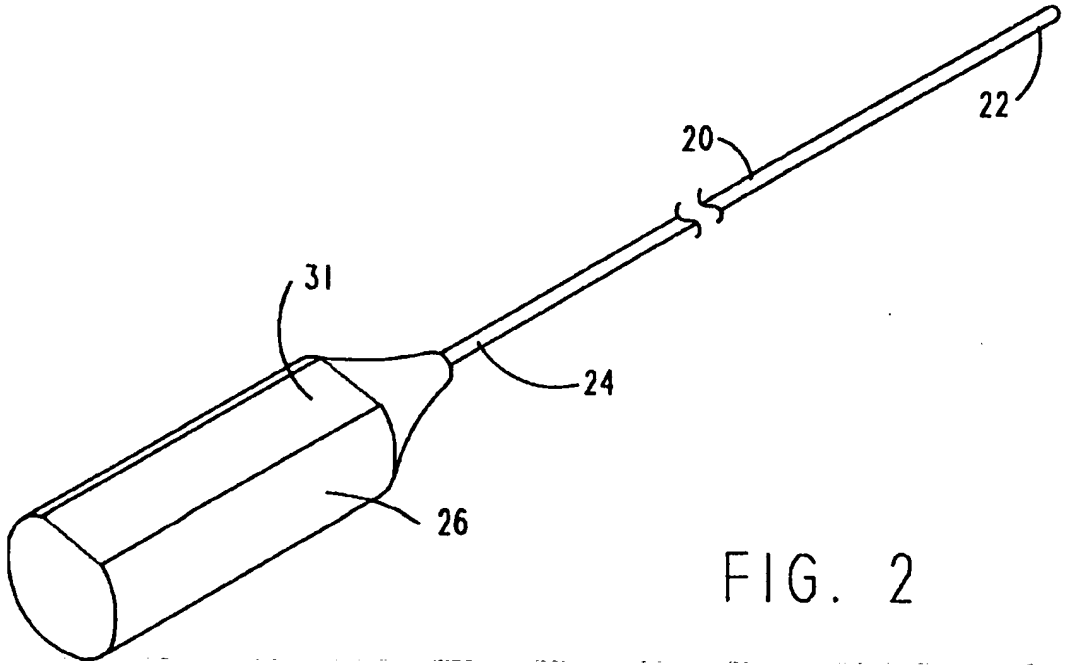


FIG. 2

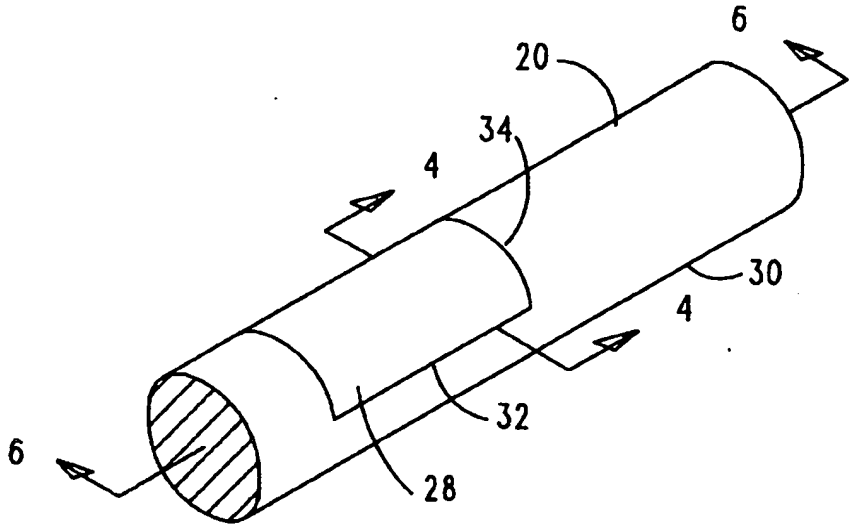


FIG. 3

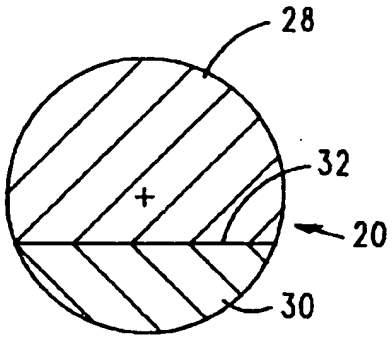


FIG. 4

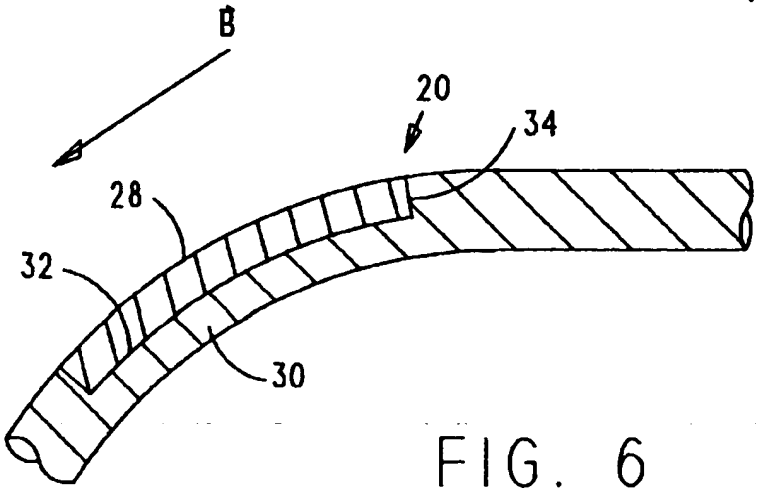


FIG. 6

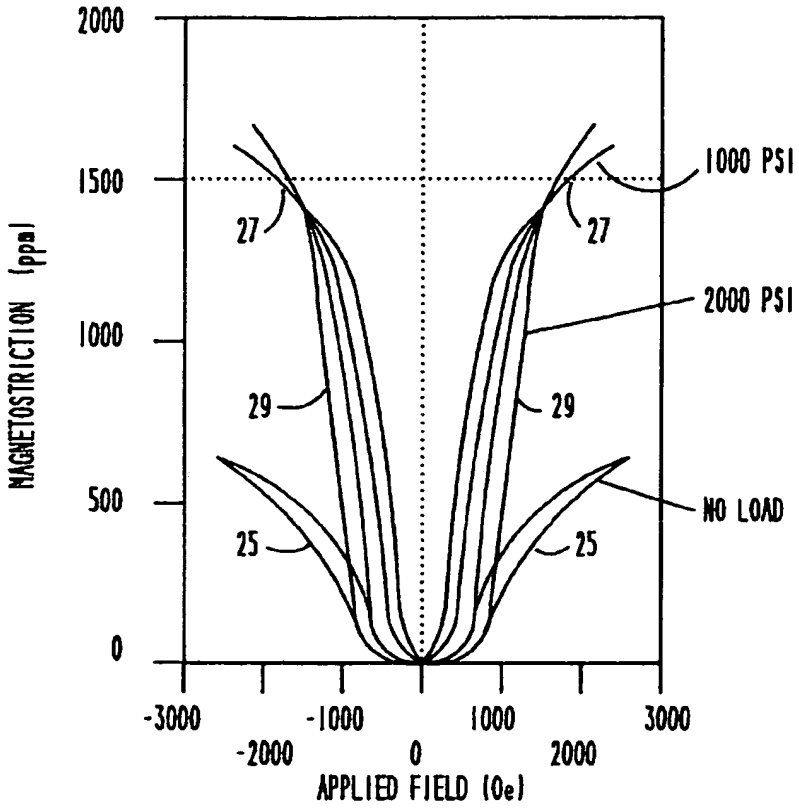


FIG. 5

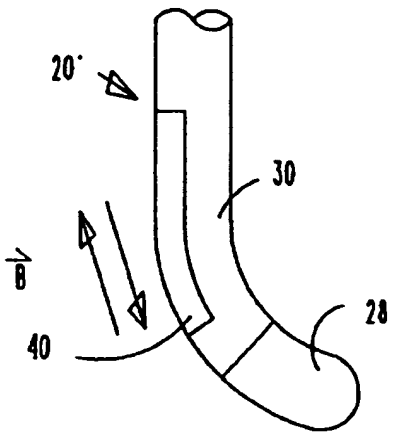


FIG. 12

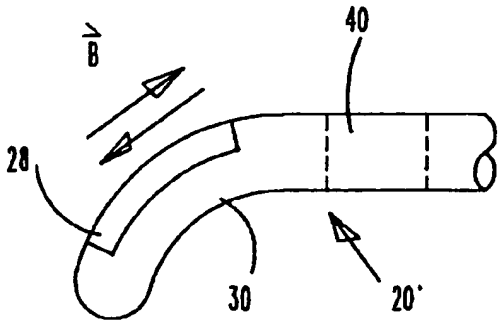


FIG. 13

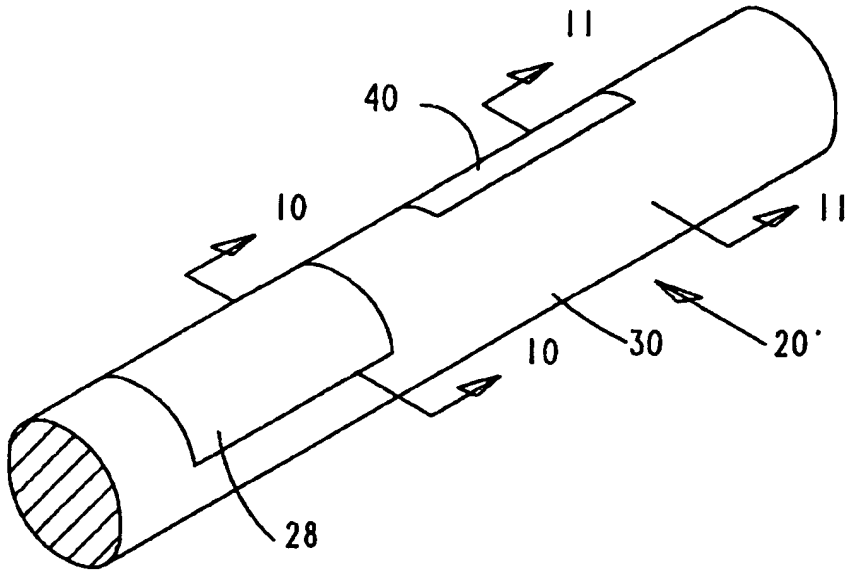


FIG. 9

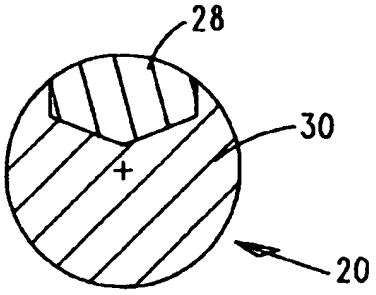


FIG. 7

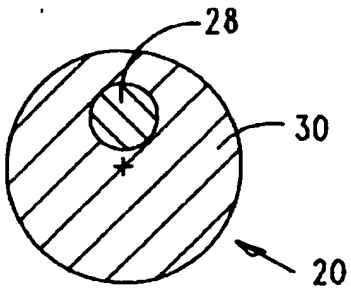


FIG. 8

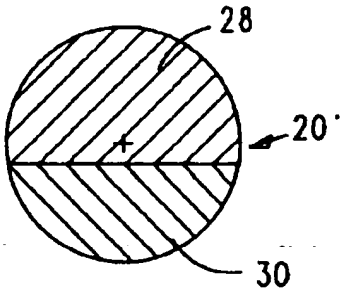


FIG. 10

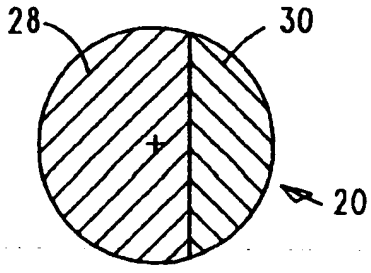


FIG. 11

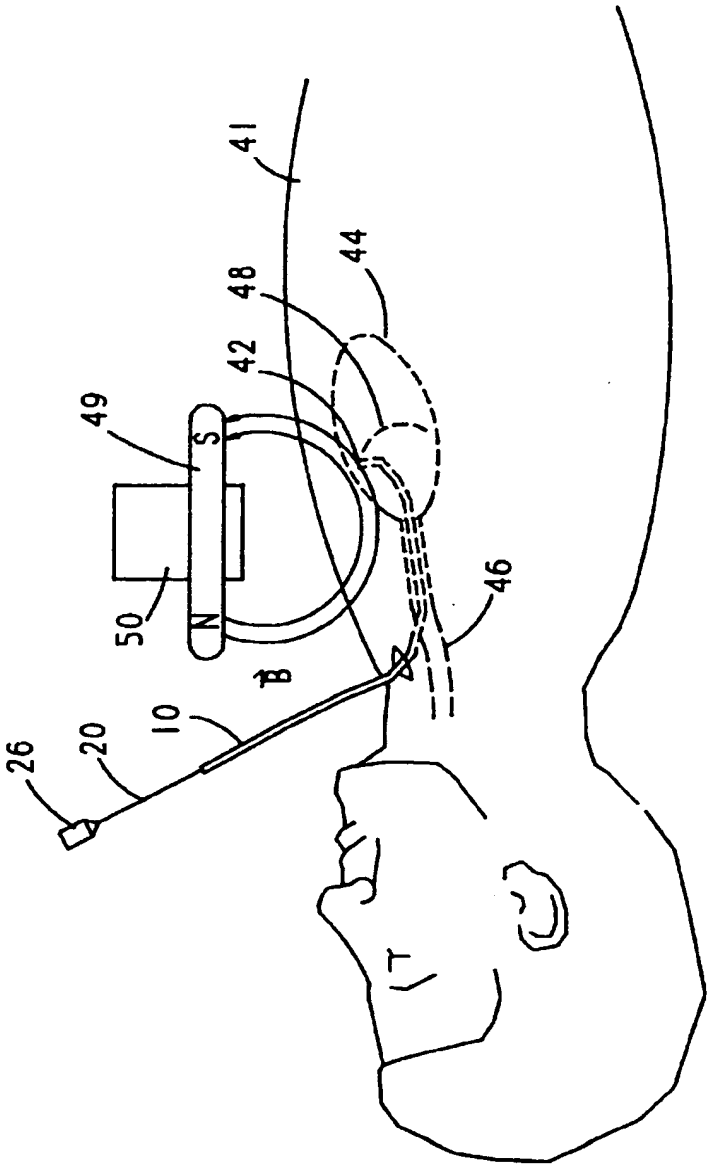


FIG. 14

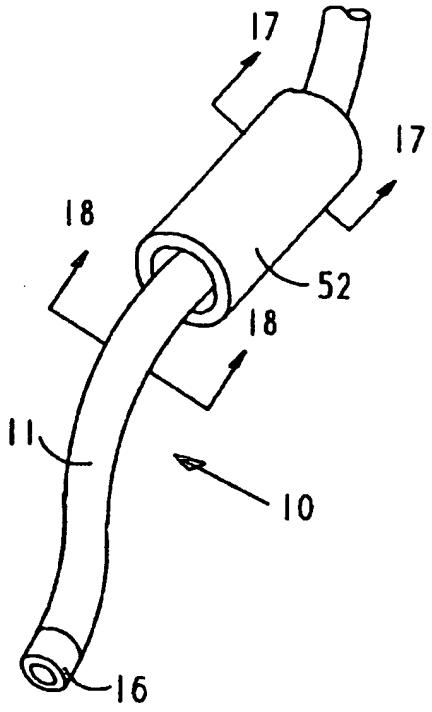


FIG. 16

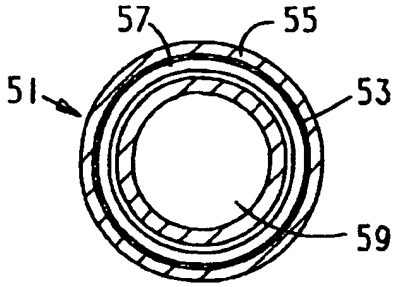


FIG. 15

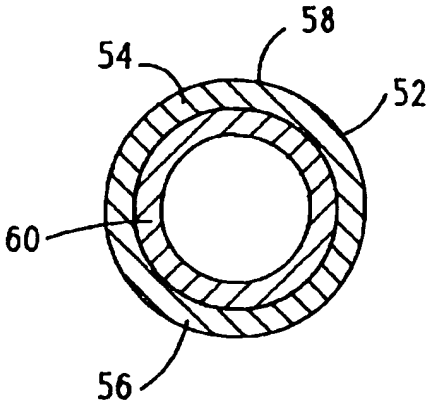


FIG. 17

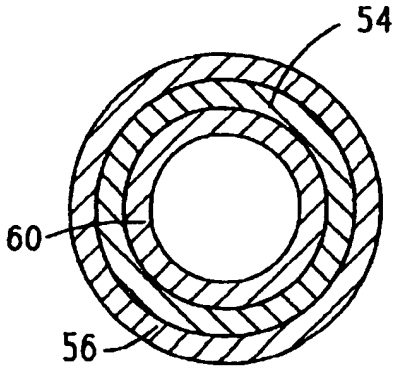


FIG. 18

STEERABLE ENDOCARDIAL LEAD USING MAGNETOSTRICTIVE MATERIAL AND A MAGNETIC FIELD

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates generally to cardiac stimulation and, more particularly, to an implantable endocardial lead assembly with apparatus for magnetically steering the lead assembly during implantation.

2. Description of the Related Art

For a variety of reasons, a person's heart may not function properly and, thus, endanger the person's well-being. Medical devices have been developed to facilitate heart function. For instance, if a person's heart does not beat properly, a cardiac stimulator may be used to provide relief. A cardiac stimulator, such as a pacemaker, is a medical device that delivers electrical stimulation to a patient's heart. A cardiac stimulator generally includes a pulse generator for creating electrical stimulation pulses and at least one conductive lead having an electrode at one end for delivering these electrical stimulation pulses to the designated portion of the heart.

Dual chamber pacemakers are capable of sensing and/or pacing in two chambers, typically the right atrium and right ventricle. Accordingly, dual chamber pacemakers typically utilize two leads—an atrial lead and a ventricular lead. The distal ends of the atrial lead and the ventricular lead are coupled to the dual chamber pacemaker. The proximal end of the atrial lead is threaded through the superior vena cava and into the right atrium of the heart. Similarly, the proximal end of the ventricular lead is threaded through the superior vena cava, through the right atrium, and into the right ventricle of the heart. Each lead includes a mechanism on its distal end that attaches to the inner wall of the heart to establish the required electrical connection between the pacemaker and the heart.

Since leads of this type reside within a beating heart, the heart imparts mechanical forces into the leads almost constantly. Such forces cause the leads to bend and flex over and over again. Because of this somewhat severe environment, such leads are typcially made to be quite flexible to withstand these forces for a prolonged period of time. By way of example, a lead may include a coiled conductor covered in polyurethane to provide the desired flexibility.

To implant a lead, a physician inserts the lead through a body vessel, such as a vein or an artery, and, using fluoroscopy, directs the lead into the heart. However, because the lead is so flexible, it cannot typically be directed through the body vessel and into the heart without some means of guiding the lead through complex vasculature. Common leads are hollow along their length. Therefore, the physician typically guides the lead into the patient's heart by manipulating a stylet that is disposed within the lead. A common stylet is stiffer than a lead, yet flexible enough to wind through the body vessels and heart chambers. Once the physician places the lead's electrode at the proper location within the heart, the physician withdraws the stylet from the lead.

In many cases, the precise placement of the lead's electrode within the heart is desirable. Conventional techniques for guiding the electrode to the desired location in the heart place great reliance on the skill of the physician in preforming and manipulating the stylet to position the electrode accurately. When a physician encounters obstructions or irregularities in the body vessels or heart of the patient, the physician must often repeatedly withdraw, reform, and advance the lead assembly until the distal end of the lead assembly is able to pass the obstruction. Because the electrode is located at the distal end of the relatively flexible lead assembly, there is often some trial and error associated with positioning the electrode next to the desired region of the myocardium.

A more automated procedure for locating a lead's electrode involves application of an external magnetic field to the patient's body to interact with a permanent magnet fixed to the lead. A hand held permanent magnet is passed over the patient's body in the vicinity of the electrode during implantation. The magnetic field associated with the hand held magnetic either propels or attracts the permanent magnetic in the lead. In either case, the lead can only be moved along a single line directly toward or directly away from the control magnet. As a consequence, such permanent magnet systems provide only crude directional control and require a rather high level of skill to locate the electrode accurately.

The present invention is directed to overcoming, or at least reducing the effects of, one or more of the aforementioned disadvantages.

SUMMARY OF THE INVENTION

In accordance with one aspect of the present invention, there is provided a stylet. The stylet includes a first member and a second member that is coupled to the first member. The second member is a magnetostrictive material.

In accordance with another aspect of the present invention, there is provided an stylet that includes a first elongated member and a second elongated member. The second elongated member is coupled longitudinally to the first elongated member. The second elongated member is a magnetostrictive material.

In accordance with another aspect of the present invention, there is provided a lead assembly for implantation in a patient. The lead assembly includes a lead adapted to transmit electrical impulses. A first member is coupled to the lead. A second member is coupled to the first member. The second member is made of a magnetostrictive material.

BRIEF DESCRIPTION OF THE DRAWINGS

Certain advantages of the invention may become apparent upon reading the following detailed description of exemplary embodiments of the invention and upon reference to the drawings in which:

FIG. 1 is a perspective view of an implantable endocardial lead assembly in accordance with the present invention;

FIG. 2 illustrates a steerable stylet and handle in accordance with the present invention;

FIG. 3 is a perspective view of a portion of the steerable stylet of FIG. 2;

FIG. 4 is a cross-sectional view the stylet taken at line 4—4 in FIG. 3;

FIG. 5 is a graph representing magnetostrictive strength versus strength of an applied magnetic field for various loads;

FIG. 6 is a side view of the stylet of FIG. 3 under the influence of one of two opposing magnetic fields;

FIG. 7 is a cross-sectional view of an alternate embodiment of the stylet of FIG. 3;

FIG. 8 is a cross-section view of another alternate embodiment of the stylet of FIG. 3;

FIG. 9 is a perspective view of a portion of another embodiment of a steerable stylet in accordance with the present invention;

FIG. 10 is a cross-sectional view of the stylet of FIG. 9 taken at line 10—10 of FIG. 9;

FIG. 11 is a cross-sectional view of the stylet of FIG. 9 taken at line 11—11 of FIG. 9;

FIG. 12 is a top view of the stylet of FIG. 9 under the influence of one of two opposing magnetic fields;

FIG. 13 is a side view of FIG. 12 showing the influence of one of two opposing magnetic fields;

FIG. 14 is a side view of an endocardial implantation of the lead assembly using a steerable stylet in accordance with the present invention;

FIG. 15 is a cross-sectional view of a special lead assembly for producing a magnetic field;

FIG. 16 is a pictorial view of an alternate embodiment of the lead assembly using a steerable stylet in accordance with the present invention;

FIG. 17 is a cross-sectional view of the lead assembly of FIG. 16 taken at line 17—17 of FIG. 16; and

FIG. 18 is a cross-sectional view of the lead assembly of FIG. 16 taken at line 18—18 of FIG. 16.

DETAILED DESCRIPTION OF SPECIFIC EMBODIMENTS

Turning now to the drawings, and referring initially to FIG. 1, an endocardial lead assembly is illustrated and generally designated by a reference numeral 10. The lead assembly 10 is designed to be inserted through a body vessel, such as the jugular vein, directly into the body for diagnostic or therapeutic purposes. The lead assembly 10 includes a lead body 11 that has a proximal end 12 that may be coupled to a cardiac stimulation device 13, such as, for example, a pacemaker or cardioverter/defibrillator. The distal end 14 of the lead body 11 is attached to an electrode assembly 16. A suture sleeve 18 is slidably disposed on the lead body 11. The suture sleeve 18 may be attached to the insertion vessel of a patient in a conventional manner.

To implant the lead assembly 10, a stylet, which is relatively stiff in comparison with the flexible lead assembly 10, is disposed within the lumen of the lead body 11. Referring to FIG. 2, one embodiment of a stylet is illustrated and generally designated by a reference numeral 20. The stylet 20 includes a distal end 22 that is normally disposed within the lead body 11 at or near the distal end 14 of the lead body 11. The proximal end 24 of the stylet 20 projects from the proximal end 12 of the lead body 11. A physician controls the longitudinal and rotational movement of the stylet 20 by using a handle 26 that is coupled to the proximal end 24 of the stylet 20.

With the stylet 20 disposed within the lead assembly 10, a physician may insert the lead assembly 10 into a body vessel of a patient and guide the lead assembly 10 into its proper position. As can be appreciated, body vessels tend to curve and flex. Accordingly, the stylet 20 is flexible enough to conform to the shape of a body vessel, yet it is stiff enough to guide the lead assembly 10 through the body vessel. Thus, when the stylet 20 is inside a body vessel, the stylet 20 typically takes on the curved shape of the body vessel, and, in the context of this discussion, these curves of the stylet 20 are referred to as "conformal curves."

To facilitate the ability of the stylet 20 to guide the lead assembly 10 through a body vessel, the stylet 20 may be non-conformally curved in situ. In other words, while the stylet 20 resides within a body vessel, the stylet 20 may be non-conformally curved by a stimulus other than the force imparted to the stylet 20 by the body vessel to produce a conformal curve. By having the ability to curve the stylet 20 in a desired direction during the implantation process, a physician may be better able to guide the stylet 20 through a curved or obstructed body vessel.

To give the stylet 20 the ability to be non-conformally curved, the stylet 20 uses at least two elements coupled together. At least one of these elements is capable of movement to produce a desired curvature in the stylet 20. FIGS. 3 and 4 illustrate one exemplary embodiment of the stylet 20. In this embodiment, the stylet 20 includes two material members 28 and 30 coupled together along at least a portion of the stylet 20. The member 28 is advantageously composed of a magnetostrictive material. The other member 30 is advantageously composed of a substrate material that is relatively non-magnetostrictive as compared with the member 28. Because magnetostrictive materials change length in response to the application of a magnetic field, the magnetostrictive member 28 will elongate in the presence of a suitable magnetic field. The magnetic field does not cause the substrate member 30 to change shape substantially, so it essentially retains its original length. Therefore, in the presence of a suitable magnetic field, the change in length of the magnetostrictive member 28 relative to the substrate member 30 produces a curvature in the stylet 20. It should also be noted that the substrate member 30 may be made of a magnetostrictive material that has a response opposite the magnetostrictive member 28 to achieve a relative change in length between the two members 28 and 30 in response to the presence of a suitable magnetic field.

The type of deformation, e.g., elongation or contraction, depends upon the type of magnetostrictive material that is used. The magnitude of the change in length of the magnetostrictive member 28 depends upon the magnitude of the magnetic field applied axially to the magnetostrictive member 28 and upon the particular magnetostrictive material used. In this embodiment, the magnetostrictive member 28 is advantageously composed of TERFENOL-D available from Etrema Products, Inc., although other suitable types of magnetostrictive materials may also be used. The magnetostrictive material TERFENOL-D also exhibits inverse magnetostriction (known as the Villari effect), a phenomenon in which a change in magnetic induction occurs when a mechanical stress is applied along a specified direction to a material having magnetostrictive properties. These measurable changes in induction enable TERFENOL-D to be used in sensing applications (such as magnetotagging) where changes in stress occur. Consequently, the flexure of the device within the body can be sensed and used as a motion transducer for diagnostic purposes.

Examples of suitable materials for the substrate member 30 may include titanium, aluminum, magnesium, and stainless steel. As with the materials used to form virtually all stylets, the material used to fashion the substrate member 30 advantageously has a relatively high flexibility to facilitate the large and frequent bending movements associated with in vivo insertions.

FIGS. 3 and 4 show one possible combination of the members 28 and 30. Since the lead assembly 10 is typically cylindrical in shape, stylets are normally cylindrical in shape also. Accordingly, the members 28 and 30 are advantageously formed into a cylindrical shape. However, it should be recognized that other shapes may be suitable, so long as the stylet 20 is capable of being inserted into the lead assembly 10.

As illustrated in FIGS. 3 and 4, the members 28 and 30 are shaped as semi-cylindrical segments having a longitudinal

interface 32 and a radial interface 34. The members 28 and 30 may be bonded together at the radial interface 34 and at least one point along the longitudinal interface 32. The members 28 and 30 may be adhesively bonded together using a suitable adhesive, such as Loctite 496 or Armco 631, although other suitable techniques, such as spot welding, hot coextrusion, or soldering, may also possibly be used.

The manner in which the members 28 and 30 are constructed may vary. One factor to be considered relates to the strength of the magnetostrictive member 28 during expansion or contraction. As illustrated in FIG. 5, the amount of magnetostriction of TERFENOL-D, measured in parts per million, varies depending upon the strength of the applied magnetic field, measured in Oerstads (Oe). The amount of magnetostriction also depends upon the initial load placed on the magnetostrictive material. As can be seen, the curves 25 illustrate relatively weak magnetostriction when no initial load is placed on the magnetostrictive material. However, as the curves 27 and 29 illustrate, the strength of magnetostriction increases when an initial preload of 1000 psi and 2000 psi, respectively, is placed on the magnetostrictive material. Accordingly, it may be desirable to place a preload on the magnetostrictive member 28 at the time it is coupled to the substrate member 30.

By way of example, a method for manufacturing a stylet 20 will be described with an initial preload in mind. First, it may be desirable to machine the magnetostrictive member 28 and the substrate member 30 to the proper sizes and configurations. For instance, if one or more magnetostrictive members 28 are to be placed at certain locations on the stylet 20, the magnetostrictive members 28 are cut and ground to the appropriate sizes. Similarly, slots for receiving the magnetostrictive members are formed in the substrate member 30. However, under certain circumstances, it may be desirable to couple the members 28 and 30 together first and machine the members 28 and 30 to a suitable size and configuration afterward.

To place a preload on the magnetostrictive member 28, the substrate member 30 is placed in a stretching device. The stretching device places a desired amount of tension on the substrate member 30. A suitable adhesive is applied to the substrate member 30, and the magnetostrictive member or members 28 are clamped to the substrate member 30. The clamped structure is cured, possibly in an oven, to complete the bonding process. Once cured, the tension is slowly released to prevent sudden stresses that may tend to delaminate the members 28 and 30. If the structure curls after the tension has been released, it may be desirable to bond it to another substrate (not shown) to provide additional strength to keep the stylet 20 relatively straight.

It is important to dispose the magnetostrictive members 28 in the correct direction to achieve the desired bending effect. Magnetostrictive material is polycrystalline. Thus, the molecular structure of magnetostrictive material is fairly well-ordered as compared to an amorphous material, but not as well-ordered as a truly crystalline material. For the magnetostrictive member 28 to elongate or contract in the longitudinal direction of the stylet 20, the polycrystalline molecules in the material should be generally perpendicular to the longitudinal surface of the substrate member 30.

FIG. 6 is a cross-sectional view taken along line 6—6 of FIG. 3 of the stylet 20 in the presence of a suitable magnetic field B. As can be seen, the magnetic field B causes the magnetostrictive member 28 to increase in length. The increase in the length of the magnetostrictive member 28 is exaggerated as shown in FIG. 6 for illustration purposes. The point or points along the interface 32 where the members 28 and 30 are bonded impact the radius of curvature of the stylet 20. For example, if the members 28 and 30 are joined at the interface proximate the vertical interface 34, the resulting radius of curvature is relatively small. Conversely, if the members 28 and 30 are joined at the interface 32, the resulting radius of curvature may be significantly larger. The radius of curvature may also be affected by other variables, such as the magnetostrictive strength of the magnetostrictive member 28, the relative cross-sectional areas of the members 28 and 30, and the stiffness of the substrate member 30. When the magnetic field B is deactivated, the magnetostrictive member 28 contracts to its original size, and the stylet 20 returns to the configuration shown in FIG. 2.

Since the stylet 20 curves in a direction dictated by the positions of the members 28 and 30 relative to one another, it is advantageous for a physician using the stylet 20 to be able to determine these relative positions. Accordingly, a handle 26 is provided at the proximal end 24 of the stylet 20, as illustrated in FIG. 2. The handle 26 is fixedly attached to the proximal end 24 of the stylet 20 so that as a physician rotates the handle 26 about the longitudinal axis of the stylet 20, the stylet 20 rotates along with the handle 26. The handle 26 advantageously includes a register that indicates the orientation of the stylet 20 to the physician during the implantation procedure. As illustrated in FIG. 2, the register may be a flattened portion 31 of the handle 26, although other shapes, such as an L-shape, or marks may be suitable as well. In this embodiment, it may be advantageous to align the flat portion 31 of the handle 26 with the stylet 20 such that the stylet curves downward when the flat portion 31 faces upward.

There may be a number of different possible combinations of shapes and sizes of the members 28 and 30. FIGS. 7 and 8 are cross-sectional views of the members 28 and 30 that show just two different possible combinations of sizes and configurations. In the embodiment shown in FIG. 7, the magnetostrictive member 28 is disposed in a four-sided groove in the substrate member 30. The four-sided groove may produce a stronger interface than the one-sided interface illustrated in FIG. 4. Another structure that may provide certain advantages, such as increased strength and better biocompatibility, is shown in FIG. 8. In this embodiment, the magnetostrictive member 28 may be enclosed within the substrate member 30.

FIGS. 9, 10, and 11 depict an alternate embodiment of the stylet, now designated by the reference numeral 20'. To simplify the description of this alternate embodiment, like reference numerals are used to identify structural elements similar to those in previously discussed embodiments. In this alternate embodiment, the stylet 20' incorporates two magnetostrictive members 28 and 40 positioned to introduce curves in the stylet 20' in two different directions. The magnetostrictive member 28 is disposed along one longitudinal plane of the stylet 20', and the other magnetostrictive member 40 is disposed along another longitudinal plane of the stylet 20'. As illustrated in this embodiment, the plane of the magnetostrictive member 28 is rotated at an angle of about 90 degrees relative to the plane of the magnetostrictive member 40, as clearly shown in FIGS. 10 and 11. Thus, as discussed below, the stylet 20' is capable of curving in two directions perpendicular to one another.

FIGS. 12 and 13 show, respectively, a top view and side view of the stylet 20' under the influence of the magnetic field B. In this embodiment, both of the magnetostrictive members 28 and 40 are composed of a magnetostrictive material that expands upon application of a magnetic field.

Activation of the magnetic field B causes the stylet **20'** to bend simultaneously in two directions. The portion of the stylet **20'** proximate the magnetostrictive member **40** bends sideways in response to the expansion of the magnetostrictive member **40**. Similarly, the portion of the stylet **20'** proximate the magnetostrictive member **28** bends downward in response to the expansion of the magnetostrictive **28**. Of course, the number and relative longitudinal and rotational positions of the magnetostrictive members, such as the members **28** and **40**, may be varied greatly to tailor the shape of the stylet **20'** to the particular body passage used for in vivo insertion.

FIG. **14** shows a side view of a human patient **41** during implantation of the lead assembly **10** into the coronary sinus **42** (shown dashed) within the heart **44** (shown dashed). As shown in FIG. **14**, the lead assembly **10** is inserted through a small incision in the body and into a body vessel, such as the jugular vein **46**. The distal end **22** of the stylet **20** is shown disposed in the right atrium **48**. The magnetic field B may be produced by a toroidally shaped coil **49** coupled to a fluoroscope **50**. When coupled to the fluoroscope **50**, the toroidally shaped coil **49** takes advantage of the convenient positioning capabilities of the fluoroscope **50**. Alternatively, the toroidally shaped coil **49** may be placed directly on the body of the patient **41** and moved independently of the fluoroscope **50**. Using either construction, it may be desirable to shield the magnetic field B to avoid distortion of the fluoroscopy imaging. The shielding may be accomplished using mu-metal or nickel plating, for instance.

During the insertion procedure, the stylet **20** is positioned rotationally by manipulating the handle **26** to place the distal end **22** of the stylet **20** in the proper orientation for insertion into the body or body vessel just prior to application of the magnetic field B. Upon activation of the magnetic field B, the distal end **22** of the stylet **20** assumes the proper curvature, and the physician may then advance the stylet **20** readily into the particular portion of the body or body vessel.

Rather than using a source for the magnetic field B that is located external to the patient **41**, a special lead assembly **51**, shown in cross-section in FIG. **15**, may be used to produce a suitable magnetic field B. The lead assembly **51** includes an inner sleeve **53** and an outer sleeve **55**, both of which are advantageously made of biocompatible material, such as silicone rubber. Sandwiched between the inner sleeve **53** and the outer sleeve **55** is a highly inductive coil **57** that is wound around the inner sleeve **53**. The inner sleeve **53** defines a central aperture **59** in the lead assembly **51** so that the stylet **20** may be inserted within the lead assembly **51**. To cause the stylet **20** to curve, an electrical current is fed into the coil **57** to produce a magnetic field B in the axial direction of the stylet **20**. Once the stylet **20** has been properly located within the patient **41**, the special lead assembly **51** may be removed, and the lead assembly **10** may be positioned by disposing it on the properly positioned stylet **20**. Of course, the regular lead assembly **10** may be used to produce the magnetic field B instead of the special lead assembly **51**. However, most known lead assemblies, such as the lead assembly **10**, have high resistance and low inductance making them generally unsuitable for producing the requisite magnetic field.

The utilization of a magnetostrictive stylet **20** may be used in a variety of in vivo implantation contexts where the peculiarities of the particular body passage or the delicacy of surrounding tissues requires careful steerage. Examples of other possible applications for the magnetically steerable stylet **20** may include intracranial placement of drug infusion catheters or shunts, insertion of subcutaneously placed supply lines for implantable infusion pumps, or in vivo placement of cryotherapeutic catheters.

In another alternate embodiment of the present invention shown in FIGS. **16**, **17**, and **18**, the magnetically steerable functionality of the stylet **20** in the aforementioned embodiments is incorporated directly into the lead body **11** of the lead assembly **10**. Referring first to FIGS. **16** and **17**, a cylindrical sleeve **52** is disposed around the lead body **11**. The sleeve **52** includes a magnetostrictive member **54** that is coupled to a substrate member **56**. The members **54** and **56** are surrounded by a biocompatible jacket **58** that may be formed from the same biocompatible material used to form the exterior **60** of the lead body **11**. The jacket **58** of the sleeve **52** may also be formed integral with the coating **60** of the lead body **11**. Alternatively, the sleeve **52** may be bonded to the coating **60** of the sleeve **11** using a biocompatible adhesive. In addition, the magnetostrictive member **54** and the substrate member **56** may be incorporated into the jacket **60** of the sleeve **11** as shown in FIG. **18**.

In operation, the sleeve **52** functions in a manner similar to the stylets **20** and **20'** disclosed above, in that the magnetostrictive member **54** expands or contracts relative to the substrate member **56** in the presence of a suitable magnetic field. Also, as with any of the aforementioned embodiments, the number size and arrangement of the magnetostrictive members **54** and the substrate members **56** may be varied depending upon the particular application. Similarly, the number and spacing of individual sleeves **52** may be varied according to the requirements of the implantation.

While the invention is susceptible to various modifications and alternative forms, specific embodiments have been shown by way of example in the drawings and have been described in detail herein. However, it should be understood that the invention is not intended to be limited to the particular forms disclosed. Rather, the invention is to cover all modifications, equivalents, and alternatives falling within the spirit and scope of the invention as defined by the following appended claims.

What is claimed is:

1. In an implantable stylet, the improvement comprising:

a first member; and

a second member comprising a magnetostrictive material, wherein in the presence of a given magnetic field, the percent change in length of said second member is different than the percent change in length of said first member, further wherein said second member is fixedly coupled to said first member to cause said implantable stylet to curve under the influence of a given magnetic field.

2. The stylet of claim **1**, wherein said first member is configured to receive said second member such that said second member is enclosed inside said first member.

3. The stylet of claim **1**, wherein said first member is an elongated member and said second member is affixed to said first member along a longitudinal interface.

4. The stylet of claim **1**, wherein said first member comprises a non-magnetic metal.

5. In an implantable stylet, the improvement comprising:

a first member;

a second member coupled to said first member, said second member comprising a magnetostrictive material, and a handle being fixedly coupled to one end of said stylet.

6. In an implantable stylet, the improvement comprising:

a first elongated member;

a second elongated member being coupled longitudinally to said first elongated member, said second elongated

member comprising a magnetostrictive material, wherein said first elongated member is secured to said second elongated member such that said implantable stylet bends when disposed in a suitable magnetic field.

7. The stylet of claim 6, wherein said second elongated member undergoes a different percent change in length than said first elongated member in response to a suitable magnetic field.

8. In an implantable stylet, the improvement comprising:

a first elongated member;

a second elongated member being coupled longitudinally to said first elongated member, said second elongated member comprising a magnetostrictive material; and

a third elongated member, said third elongated member being coupled longitudinally to said first elongated member, said third elongated member comprising a magnetostrictive material.

9. The stylet of claim 8, wherein said second elongated member and said third elongated member are disposed in a predetermined angular relationship relative to one another.

10. In an implantable stylet the improvement comprising:

a first elongated member;

a second elongated member being coupled longitudinally to said first elongated member, said second elongated member comprising a magnetostrictive material; and

a handle being fixedly coupled to one end of said stylet.

11. A lead assembly for implantation in a patient, comprising:

a lead adapted to transmit electrical impulses;

a first member coupled to said lead; and

a second member coupled to said first member, said second member comprising a magnetostrictive material.

12. The lead assembly of claim 11, wherein said first member is an elongated member and said second member is affixed to said first member along a longitudinal interface.

13. The lead assembly of claim 11, wherein said first member comprises a non-magnetic metal.

14. The lead assembly of claim 11, wherein said second member undergoes a different percent change in length than said first member in response to a suitable magnetic field.

15. The lead assembly of claim 14, wherein said lead assembly is configured to curve in response to said suitable magnetic field, the degree of curvature depending on the strength of said suitable magnetic field.

* * * * *

US006385472B1

(12) **United States Patent**
Hall et al.

(10) **Patent No.: US 6,385,472 B1**
(45) **Date of Patent: May 7, 2002**

(54) **MAGNETICALLY NAVIGABLE TELESCOPING CATHETER AND METHOD OF NAVIGATING TELESCOPING CATHETER**

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(73) Assignee: **Stereotaxis, Inc.**, St. Louis, MO (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/393,521**

(22) Filed: **Sep. 10, 1999**

(51) **Int. Cl.**[7] **A61B 5/04**
(52) **U.S. Cl.** **600/374**; 600/585; 606/41; 607/122; 604/528
(58) **Field of Search** 7/103, 122, 585, 7/373, 374; 600/12, 13, 14, 424; 604/528

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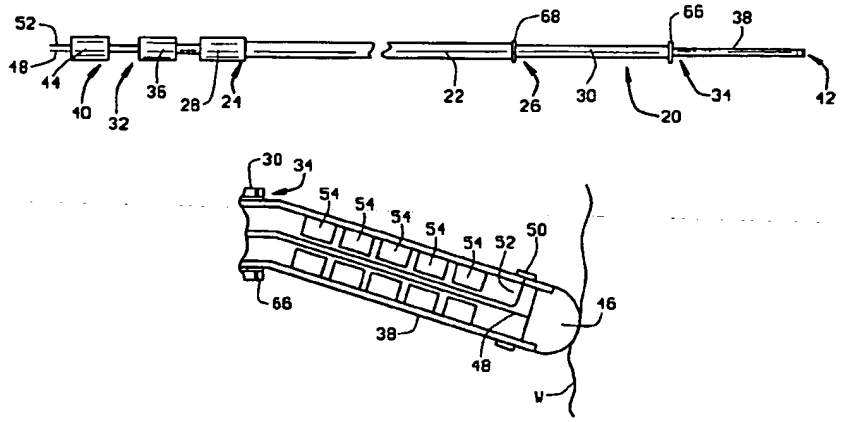
Assistant Examiner—David M. Ruddy
(74) *Attorney, Agent, or Firm*—Harness Dickey & Pierce, P.L.C.

(57) **ABSTRACT**

A magnetically navigable catheter includes a sheath having a proximal end and a distal end, and an extension member having a proximal end and a distal end, slidably mounted in the sheath so that the distal end portion of the extension member telescopes from the distal end of the sheath. The distal end portion of the extension member being relatively more flexible than the distal end of the sheath. There may be one or more electrodes on the distal end of the extension member. There is also at least one magnet, and preferably more than one magnet, on the distal end portion of the extension member to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field. The catheter preferably also includes a sleeve, having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath, so that the sleeve can be selectively extended and retracted relative to the sheath, and the extension member can be selectively extended and retracted relative to the sleeve. According to the method of this invention, the distal end of the electrode catheter is introduced into the part of the body where the electrode will be used to contact the specific body structures, and the electrode is moved into contact with the body structure by applying an external magnetic field and selectively telescoping the extension member relative to the sheath to bring the electrode on the distal end of the extension member into contact with the specific body structure.

18 Claims, 3 Drawing Sheets



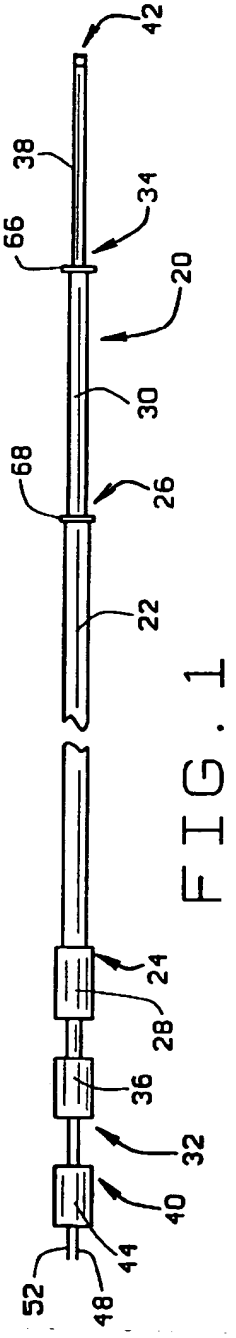


FIG. 1

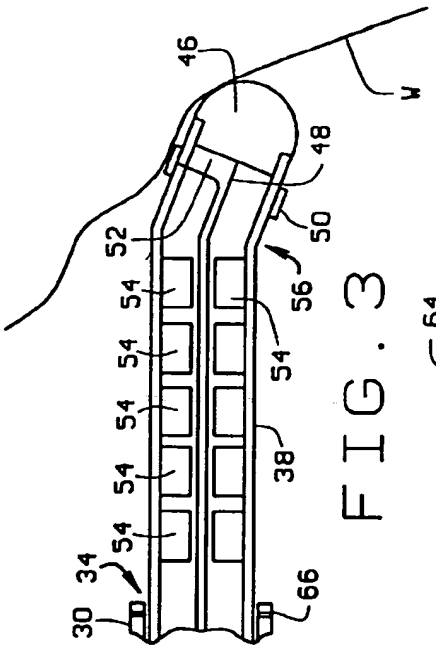


FIG. 3

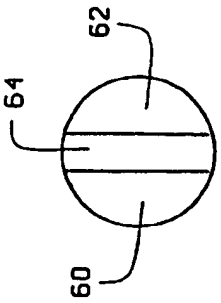


FIG. 5

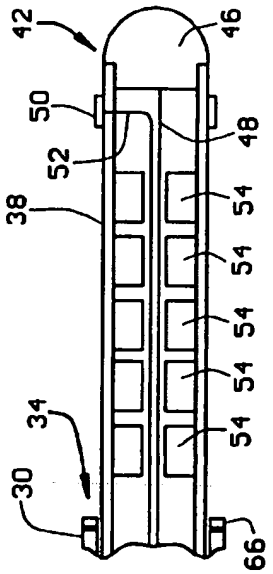


FIG. 2

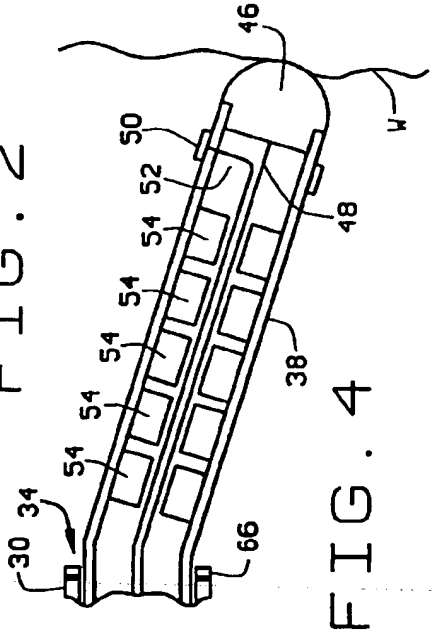


FIG. 4

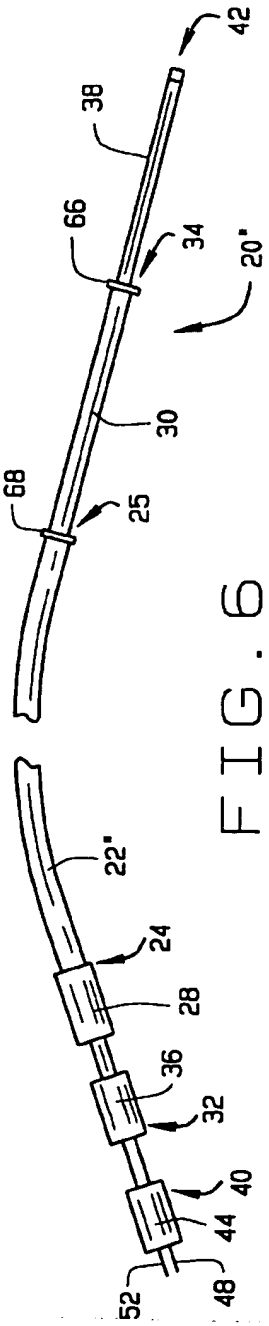


FIG. 6

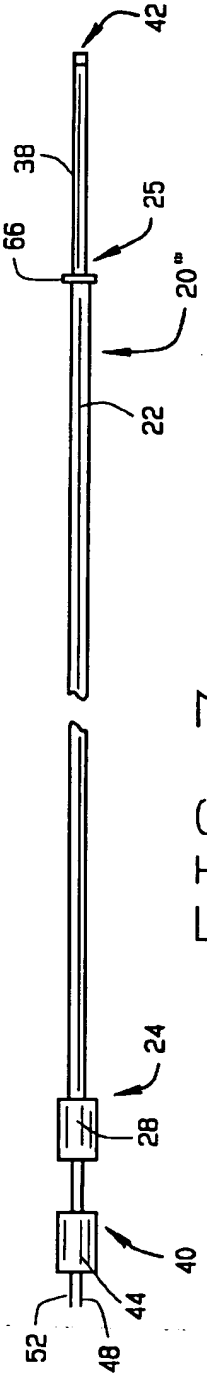


FIG. 7

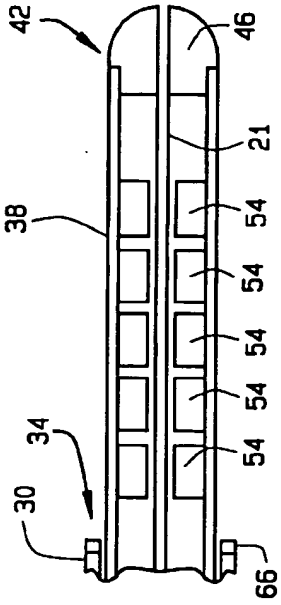


FIG. 9

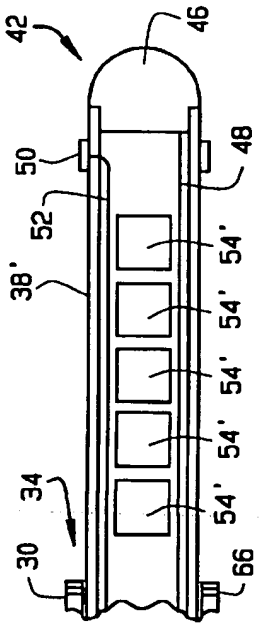


FIG. 8

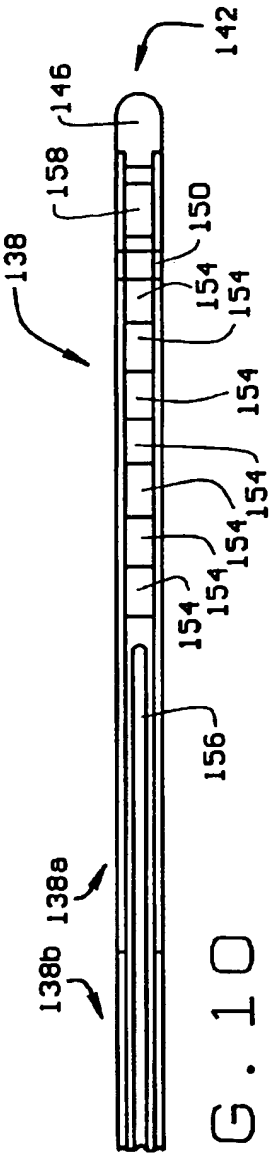


FIG. 10

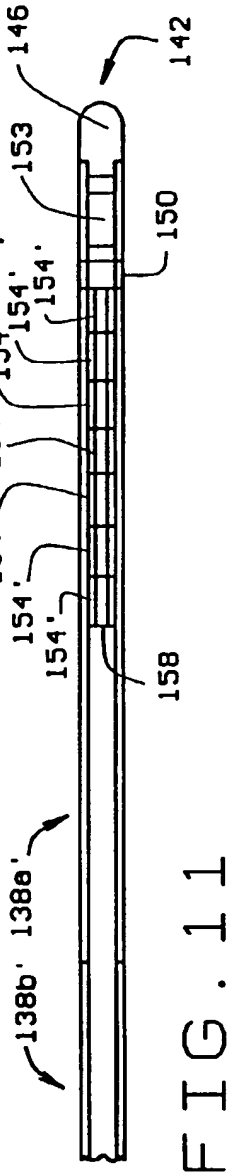


FIG. 11

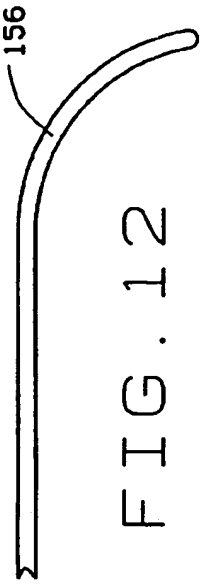


FIG. 12

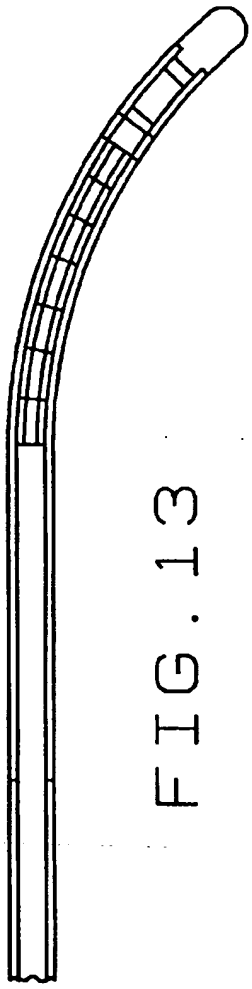


FIG. 13

MAGNETICALLY NAVIGABLE TELESCOPING CATHETER AND METHOD OF NAVIGATING TELESCOPING CATHETER

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a divisional patent application of U.S. patent application Ser. No. 09/393,521, filed Sep. 10, 1999, which is a continuation-in-part of U.S. patent application Ser. No. 09/151,615, filed Sep. 11, 1998 now abandoned.

FIELD OF THE INVENTION

This invention relates to a magnetically navigable telescoping catheter and a method of magnetically navigating a telescoping catheter within open body spaces.

BACKGROUND OF THE INVENTION

Many medical procedures require the ability to accurately navigate medical devices inside the body. In the past, this has been accomplished with mechanically steerable devices. More recently, magnetically navigable medical devices have been developed that can be navigated with an externally applied magnetic field.

However, previously available navigable devices and navigation methods are only marginally acceptable for some procedures where high precision is required. For example, in certain cardiac procedures such as mapping (recording electrical impulses on the surface of the heart); pacing (inducing electrical impulses of the surface of the heart); and ablation (applying RF energy to the heart tissue to ablate the tissue to block stray electrical signals that cause arrhythmias) an electrode must be precisely controlled to contact specific points on the heart. One treatment of cardiac arrhythmias relies upon the formation of a continuous linear lesion from a series of contiguous spot lesions. Such a procedure can be extremely tedious and time consuming with previously available devices and navigation methods.

Examples of mechanically controlled catheters for such procedures include Avitall, U.S. Pat. Nos. 5,354,297, 5,327,905, and 5,642,736; Webster, U.S. Pat. No. Re 34,502; West et al., U.S. Pat. No. 5,318,525; and Webster, Jr., U.S. Pat. No. 5,626,136. These mechanically actuable catheters typically have a limited number of directions of movement. Moreover to navigate the distal end of the catheter to a particular point, the catheter had to be rotated, but rotation of the proximal end of the catheter did not always directly translate to rotation at the distal end, particularly where the path of the catheter was convoluted. Moreover, twists and turns in the catheter would impair or eliminate the ability to control the distal end of the catheter.

Magnets have also been used in such devices. Scheinman, U.S. Pat. No. 5,429,131 and Grayzel, U.S. Pat. No. 4,809,731. However, not for navigation.

SUMMARY OF THE INVENTION

The present invention relates to a magnetically navigable telescoping catheter, and to a method of navigating such catheter in the body. Generally, the magnetically navigable telescoping catheter of the present invention comprises a sleeve having a proximal end and a distal end. An extension member having a proximal end and a distal end is slidably mounted in the sleeve so that the distal end portion of the extension member telescopes from the distal end of the sleeve. The distal end portion of the extension member is relatively more flexible than the distal end of the sleeve. At least one magnet is positioned on the distal end portion of the extension member to allow the distal end of the extension member to be oriented by the application of an externally applied magnetic field. The position of the distal tip of the catheter can be controlled by the controlled application of a magnetic field to orient the distal end of the extension member, and telescoping the extension member into and out of the sleeve. At least one electrode is positioned on the distal end of the extension member.

In accordance with a preferred embodiment of this invention, a sheath is also provided, and the sleeve is slidably mounted in the sheath so that the distal end of the sleeve can telescope relative to the distal end of the sheath. In navigating the catheter of the preferred embodiment, in addition to the direction control provided by the controlled application of a magnetic field and the telescoping of the extension member relative to the sleeve, the user can also telescope the sleeve relative to the sheath to control the position of the distal end of the extension member. This gives the user a first adjustable length whose direction is controlled by the direction of the magnetic field, and a second adjustable length substantially unaffected by the direction of the magnetic field.

The catheter can be provided with one or more electrodes for cardiac mapping, pacing, or ablation. Alternatively, the catheter can be used in some other procedure such as the delivery of therapeutic agents.

According to the method of this invention, the distal end of the extension member is navigated to the site in the body. Once in the desired location, a magnetic field is applied to orient the distal end portion of the extension member, and the distal end is navigated to a precise location by the relative telescoping of the extension member relative to the sleeve, and in the preferred embodiment also by the relative telescoping of the sleeve relative to the sheath.

With this method, an electrode on the end of the distal end of the extension member can be navigated to contact specific parts of the body, for example the chambers of the heart, to bring an electrode into contact with the tissue for mapping, pacing, or ablation.

The telescoping motion and magnetic guidability of the electrode catheter of the present invention allows superior control of the distal end of the catheter, without regard to the path of the catheter. The improved navigation is both faster, reducing procedure times, and more accurate, allowing the procedures to be successfully completed. However the catheter is of relatively simple and reliable construction. These and other features and advantages will be in part apparent and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a top plan view of a catheter constructed according to the principles of this invention;

FIG. 2 is an enlarged longitudinal cross-sectional view of the extension member; taken along the plane of line 2—2 in FIG. 1;

FIG. 3 is an enlarged longitudinal cross-sectional view of the extension member, showing the flex point on the extension member between the magnets and the electrodes;

FIG. 4 is an enlarged longitudinal cross-sectional view of the extension member, showing the flex point on the extension member between magnets and the distal end of the sleeve;

FIG. 5 is a distal end elevation view of an alternate construction of the catheter, showing an alternate arrangement of the electrodes;

FIG. 6 is a top plan view of an alternate construction of the electrode catheter in which the sheath is curved;

FIG. 7 is a top plan view of an alternate construction of the electrode catheter without a sleeve;

FIG. 8 is longitudinal cross-sectional view of an alternate construction of the extension member;

FIG. 9 is a longitudinal cross-sectional view of an alternative construction of a telescoping catheter;

FIG. 10 is a longitudinal cross-sectional view of an alternate construction of the extension member adapted for use with a stylette;

FIG. 11 is a longitudinal cross-sectional view of an alternate construction of the extension member adapted for use with a stylette;

FIG. 12 is a longitudinal cross-sectional view of a stylette adapted for use with the extension members shown in FIGS. 10 or 11; and

FIG. 13 is a longitudinal cross-sectional view of a stylette adapted for use with the extension members shown in FIG. 11.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

A catheter constructed according to the principles of the present invention is indicated generally as **20** in FIG. **1**. As shown in the figures and described herein, catheter **20** is an electrode catheter having one or more electrodes thereon, but this invention is not so limited and the catheter can be used for other purposes, for example the delivery of diagnostic or therapeutic agents. FIG. **9** shows such a catheter **20'** with a central passage **21** for the delivery of diagnostic or therapeutic agents.

The electrode catheter **20** of the preferred embodiment comprises a sheath **22** having a proximal end **24** and a distal end **26**. The sheath **22** is preferably about 120 cm long. There is a connector block **28** at the proximal end of the sheath **22**. The sheath **22** is preferably made from conventional sheath material, with an outside diameter of about 9 French. As shown in FIG. **6**, instead of the straight sheath **22**, in an alternate construction of the electrode catheter **20"**, the sheath **22"** may be precurved, for example to facilitate a transseptal approach to the left atrium. A sleeve **30** having a proximal end **32** and a distal end **34** is slidably mounted in the sheath **22** so that the distal end portion of the sleeve telescopes from the distal end **26** of the sheath. The sleeve **30** is preferably about 125 cm long. There is a connector block **36** at the proximal end of the sleeve **30**. The sleeve **30** is preferably made from a conventional sheath material, with an outside diameter of about 8 French. (In an alternate construction of the electrode catheter **20'"** as shown in FIG. **7**, there is no sleeve **30**.)

An extension member **38**, having a proximal end **40** and a distal end **42** is slidably mounted in the sleeve **30** so that the distal end portion of the extension member telescopes from the distal end **34** of the sleeve. There is a connector block **44** at the proximal end of the extension member **38**. The extension member **38** is preferably a tube, made from a conventional catheter material, with an external diameter of about 7 French. The extension member is preferably about 130 cm long. The distal end portion of the extension member **38** is generally relatively more flexible than the distal end portion of the sleeve **30**. In one alternate construction the entire extension member **38** is flexible. In a second alternate construction, the portion of the extension member containing the magnets (as discussed below) is relatively rigid, while the portion of the extension member just proximal to the magnets is flexible to allow the extension member to flex. At least one electrode is positioned on the distal end of the extension member **38**. As shown in FIG. **2**, in the preferred embodiment there is a first electrode **46** on the distal end of the extension member **38**, having a generally hemispherical shape. This rounded shape facilitates navigation, and prevents damage to the surfaces that the distal end of the extension member contacts. A lead wire **48** extends from the electrode **46**, through the extension member **38**, to the proximal end **40** of the extension member. A second electrode **50**, in the form of an annular band, extends circumferentially around the distal end portion of the extension member **38**. A lead wire **52** extends from the electrode **50**, through the extension member **38**, to the proximal end **40** of the extension member. The lead wires **48** and **52** can be connected to a measuring device to measure electrical potential between the electrodes. Alternatively, the lead wires **48** and **52** can be used to force a current through the tissue for electrical pacing of the heart. Lead wire **48** can also be connected to a source of RF energy to provide such energy to electrode **46** to ablate tissue in contact with the electrode. Additional electrodes, or electrodes in other configurations and arrangements can be provided. For example, in the alternate construction shown in FIG. **5**, the distal end **42** of the extension member **38** can be provided with two electrodes **60** and **62**, separated and electrically insulated from each other by a generally diametrically extending partition **64**.

At least one magnet is positioned on the distal end portion of the extension member **38** to allow the distal end **42** of the extension member to be oriented by the application of an externally applied magnetic field. The externally applied magnetic field may be applied, for example with a magnetic surgery system like that disclosed in co-pending U.S. patent application Ser. No. 08-920,446, filed Aug. 29, 1997, entitled Method and Apparatus for Magnetically Controlling Motion Direction of a Mechanically Pushed Catheter. In this preferred embodiment, there are a plurality of magnets **54** inside the tube forming the extension member **38**. Each of the magnets **54** preferably has an annular shape with a central passage through which the lead wires **48** and **52** may pass. As shown in FIG. **8**, in an alternate construction of the extension member **38'**, the magnets **54'** are solid with a smaller diameter, allowing wires **48** and **52** to pass between the magnets and the wall of the extension member **38'**. The magnets **54** are preferably closely spaced to each other, and may even be touching so that they are held together by mutual magnetic attraction. This configuration maximizes the volume of magnetic material while keeping the extension member **38** flexible. The magnets **54** are spaced proximally from the electrodes **46** and **50** on the distal end of the extension member to form a flex point **56** in the extension member between the magnets and the electrodes. Similarly, the extension member **38** preferably can telescope out of the sleeve **30** beyond the most proximal of the magnets **54** to form a flex point **58** in the extension member between the magnets and the distal end of the sleeve.

The electrodes **46** and **50** and magnets **54** are typically radio-opaque so that the distal end portion of the extension member is visible in real time fluoroscope images. The distal end **34** of the sleeve **30** is preferably provided with a radio-opaque band **66**, and the distal end **26** of the sheath **22** is provided with a radio-opaque band **68**, so that the distal ends of the sleeve and the shaft are also visible under

fluoroscopy. This helps the user navigate the distal end **42** of the extension member into the desired position. The procedure can be viewed in one or more two-dimensional images, or conventional image processing can be used to render a three dimensional view of the device which could then be placed within a three-dimensional image set (e.g., from MRI) of the body portion. The radio-opaque electrodes **46** and **50**, magnets **54**, and bands **66** and **68** also facilitate automating navigation of the distal end, by providing feedback of the position of the distal ends of the sleeves.

In operation the distal end of the device **20** is navigated to the site in the body where the procedures, such as an atrial mapping, pacing, and ablation, are to occur. The device **20** extends into a heart chamber, for example into the right atrium from the inferior vena cava, into the left atrium from the right atrium via a transseptal puncture, or into the right ventricle via the tricuspid valve or into the left ventricle via the aortic valve. Once the distal end portion of the device is in the chamber, a magnetic field is applied to provide an orienting force to the extension member **38**. The magnetic field causes the magnets **54** to align in the selected direction. The electrode on the distal end of the extension member **38** is then manipulated to the desired location by selectively telescoping the sleeve **30** relative to the sheath **22**, and the extension member relative to the sleeve. Depending on the navigation system being used, the manipulation could be an iterative process, whereby the navigation system constantly tweaks the direction of the magnetic field, based on the location of the tip of the extension member and the desired target location. It would also be possible to automate the process, allowing the surgeon to input either a desired direction or location, and using a computer to control the magnetic field and the telescoping of the sleeve and the extension member.

In the case of electrophysiologic mapping or pacing, as shown in FIG. **3** the distal end portion of the extension member **38** is urged against the wall W of the chamber to cause the end to flex at flex point **56** proximal of the electrodes **46** and **50** but distal of the magnets **54**. This allows both electrodes **46** and **50** to lie against the wall W of the chamber, and allows the measurement of monopolar or bipolar electrical impulses in the wall of the atrium between the electrodes. By carefully navigating the distal end portion of the extension member **38** across the surface of the chamber, the entire cardiac chamber can be electrically mapped.

In the case of therapeutic ablation, as shown in FIG. **4**, the electrode **46** on the distal end of the extension member **38** can be precisely navigated along the wall of the atrium, where RF energy can be applied to ablate the underlying tissue. The precise navigational control permitted by the electrode catheter allows both focal lesions and the creation of lines of continuous lesions to be formed in the chamber, blocking the path of stray electrical signals that cause the arrhythmia. Such continuous lines of lesions were extremely difficult, if not impossible to form, particularly in the left atrium, with prior mechanically steerable catheters.

An alternate construction of the extension member **38** is indicated generally as **138** in FIG. **10**. Extension member **138**, having a proximal end and a distal end **142** is slidably mounted in a sleeve (not shown) so that the distal end portion of the extension member telescopes from the distal end of the sleeve. The extension member **138** is preferably a tube made from a conventional catheter material with an external diameter of about 7 French. The extension member is preferably about 130 cm long. The tube preferably comprises sections of different stiffness to facilitate navigation of the catheter. In the preferred embodiment, the distal section **138***a* is made from a very flexible vinyl or polyethylene or polyurethane, and the proximal section **138***b* is made from a relatively stiffer material such as nylon. There is a first electrode **146** on the distal end of the extension member **138**, having a generally hemispherical. This rounded shape facilitates navigation, and prevents damage to the surfaces that the distal end of the extension member contacts. A lead wire extends from the electrode **146**, through the extension member **138**, to the proximal end of the extension member. A second electrode **150**, in the form of an annular band, extends circumferentially around the distal end portion of the extension member **138**. A lead wire extends from the electrode **150**, through the extension member **138**, to the proximal end of the extension member. The lead wires can be connected to a measuring device to measure electrical potential between the electrodes. Alternatively the lead wires can be used to force a current through the tissue for electrical pacing of the heart. The lead wires can also be connected to a source of RF energy to provide such energy to the electrodes to ablate tissue in contact with the electrodes. Additional electrodes, or electrodes in other configurations and arrangements can be provided.

A localization device **153** is preferably incorporated into the extension member **138** so that the location of the extension member, and preferably both the location and orientation of the extension member, can be determined. In the preferred embodiment, the localization is a magnet device, such as a triaxial coil receiver for AC electromagnetic fields, but the localization could be done with some other device, such as ultrasound devices.

A plurality of magnets **154** are positioned on the distal end portion of the extension member **138** to allow the distal end **142** of the extension member to be oriented by the application of an externally applied magnetic field. The tube forming the extension member **138** is open proximal to the magnets to receive at the distal end of the stylette **156** to stiffen, shape, or guide the distal end of the extension member. The stylette **156** is inserted into the proximal end of extension member **138** and advanced to the distal end where the stylette in the lumen of the tube forming the extension member selectively stiffens the extension member and/or shapes the extension member to facilitate navigation. The distal end of the stylette can be preformed for a particular navigation and inserted into the extension member **138** to shape the extension member for the navigation. The stylette can also be used to push the extension member. The stylette can be selectively inserted and removed to selectively temporarily stiffen and temporarily soften the distal end of the extension member to facilitate navigation.

An alternate construction of the extension member **138** is indicated generally as **138'** in FIG. **11**. Extension member **138'** is similar in construction to extension member **138**, and corresponding parts are identified with corresponding reference numerals. However, rather than cylindrical magnets **154**, extension member **138'** has annular magnets **154'**, whose central opening are aligned to form a passage **158** for the stylette **156**. The stylette **156** can be inserted through the proximal end of extension member **138'** and into the passage **158** to selectively stiffen and/or shape the distal portion of the extension member **138**. As shown in FIG. **12**, the distal end portion of the stylette can be bent, and as shown in FIG. **13** it can be inserted into the extension member **138'** to shape the distal end of the extension member. The passage **158** also allow the stylette **156** to apply a pushing force closer to the distal end of the extension member.

The movement of the sheath, the extension member, and even the stylette, can be automated and operated by motor instead of manually, if desired.

What is claimed is:

1. A method of navigating the distal end of a catheter within the body into contact with specific body structures, the method comprising:

providing a magnetically navigable catheter comprising a sheath having a proximal end and a distal end, an extension member having a proximal end and a distal end, the extension member being slidably mounted in the sheath so that the distal end portion of the extension member telescopes from the distal end of the sheath, the distal end portion of the extension member being relatively more flexible than the distal end of the sheath; and at least one magnet on the distal end portion of the extension member;

introducing the distal end of the magnetically navigable catheter into the part of the body where the distal end will be used to contact the specific body structures;

moving the distal end into contact with a body structure by applying an external magnetic field and selectively telescoping extension member relative to the sheath to bring the electrode on the distal end of the extension member into contact with the specific body structure.

2. The method according to claim 1 wherein the catheter comprises an electrode on the distal end of the extension member, and wherein the step of moving the distal end into contact with a body structure comprises moving the electrode into contact with the body structure.

3. The method according to claim 1 wherein the magnetically navigable catheter further comprises a sleeve having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath, and the extension member being slidably mounted in the sleeve in the sheath, and wherein the step of moving the electrode into contact with the body includes selectively telescoping the extension member relative to the sleeve and the sleeve relative to the sheath.

4. The method according to claim 1 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member to stiffen the extension member.

5. The method according to claim 1 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a pre-shaped stylette into the lumen in the extension member to shape the extension member to facilitate navigation of the extension member.

6. The method according to claim 1 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member and pushing the stylette to push the extension member.

7. An magnetically navigable electrode catheter comprising:

a sheath having a proximal end and a distal end;

a sleeve having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath;

an extension member having a proximal end and a distal end, the extension member being slidably mounted in the sleeve so that the distal end portion telescopes from the distal end of the sleeve, the distal end portion of the extension member being relatively more flexible than the distal end of the sleeve;

at least one electrode on the distal end of the extension member; and

the distal end portion of the extension member comprises a hollow flexible tube with a plurality of magnets disposed therein to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field the plurality of magnets being relatively closely spaced within the hollow flexible tube, but spaced proximally from the at least one electrode on the distal end to form a flex point in the extension member between the magnets and the at least one electrode.

8. An magnetically navigable electrode catheter comprising:

a sheath having a proximal end and a distal end;

a sleeve having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath;

an extension member having a proximal end and a distal end, the extension member being slidably mounted in the sleeve so that the distal end portion telescopes from the distal end of the sleeve, the distal end portion of the extension member being relatively more flexible than the distal end of the sleeve;

at least one electrode on the distal end of the extension member; and

the distal end portion of the extension member comprises a hollow flexible tube with a plurality of magnets disposed therein to allow the distal end of extension member to be oriented by the application of an externally applied magnetic field the plurality of magnets being relatively closely spaced within the hollow flexible tube, and wherein the tube can telescope out of the sleeve beyond the most proximal of the magnets, to form a flex point in the extension member between the magnets and the sleeve.

9. A method of mapping the electrical characteristics of the left atrium of the heart comprising:

providing a magnetically navigable electrode catheter comprising a sleeve having a proximal end and a distal end, an extension member having a proximal end and a distal end, the extension member being slidably mounted in the sleeve so that the distal end portion telescopes from the distal end of the sleeve, the distal end portion of the extension member being relatively more flexible than the distal end of the sleeve;

at least one electrode on the distal end of the extension member; and at least one magnet on the distal end portion of the extension member;

introducing the distal end of the magnetically navigable electrode catheter into left atrium;

moving the electrode into contact with a selected point on the surface of the left atrium by applying an external magnetic field and selectively telescoping extension member relative to the sleeve to bring the electrode on the distal end of the extension member into contact with the specific point on the surface of the left atrium;

measuring the electrical characteristics of the left atrium between the electrodes.

10. The method according to claim 9 wherein the magnetically navigable electrode catheter further comprises a sheath having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath, and wherein the step of moving the electrode into contact with a selected point on the surface of the left atrium includes selectively telescoping the sleeve relative to the sheath.

11. The method according to claim 9 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member to stiffen the extension member.

12. The method according to claim 9 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a pre-shaped stylette into the lumen in the extension member to shape the extension member to facilitate navigation of the extension member.

13. The method according to claim 9 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member and pushing the stylette to push the extension member.

14. A method of therapeutically ablating tissue in the left atrium of the heart comprising:

providing a magnetically navigable electrode catheter comprising a sleeve having a proximal end and a distal end, an extension member having a proximal end and a distal end, the extension member being slidably mounted in the sleeve so that the distal end portion telescopes from the distal end of the sleeve, the distal end portion of the extension member being relatively more flexible than the distal end of the sleeve;

at least one electrode on the distal end of the extension member; and at least one magnet on the distal end portion of the extension member;

introducing the distal end of the magnetically navigable electrode catheter into left atrium;

moving the electrode into contact with a selected point on the surface of the left atrium by applying an external magnetic field and selectively telescoping extension member relative to the sleeve to bring the electrode on the distal end of the extension member into contact with the specific point on the surface of the left atrium; and

applying an RF signal to the tissue in contact with the electrode to ablate the tissue.

15. The method according to claim 14 wherein the magnetically navigable electrode catheter further comprises a sheath having a proximal end and a distal end, the sleeve being slidably mounted in the sheath so that the distal end portion of the sleeve telescopes from the distal end of the sheath, and wherein the step of moving the electrode into contact with a selected point on the surface of the left atrium includes selectively telescoping the sleeve relative to the sheath.

16. The method according to claim 14 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member to stiffen the extension member.

17. The method according to claim 14 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a pre-shaped stylette into the lumen in the extension member to shape the extension member to facilitate navigation of the extension member.

18. The method according to claim 14 wherein the extension member has a lumen extending at least partly therethrough, the method comprising inserting a stylette into the lumen in the extension member and pushing the stylette to push the extension member.

* * * * *

US006522909B1

(12) **United States Patent**
Garibaldi et al.

(10) **Patent No.: US 6,522,909 B1**
(45) **Date of Patent: Feb. 18, 2003**

(54) **METHOD AND APPARATUS FOR MAGNETICALLY CONTROLLING CATHETERS IN BODY LUMENS AND CAVITIES**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/370,067**

(22) Filed: **Aug. 6, 1999**

Related U.S. Application Data

(60) Provisional application No. 60/095,710, filed on Aug. 7, 1998.

(51) **Int. Cl.**[7] **A61B 5/05**

(52) **U.S. Cl.** **600/424**; 600/117; 600/407; 128/899; 324/207.11

(58) **Field of Search** 600/424, 407, 600/425, 117; 324/207.11, 200, 207.22; 128/899

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Primary Examiner—Marvin M. Lateef
Assistant Examiner—Runa Shah Qaderi

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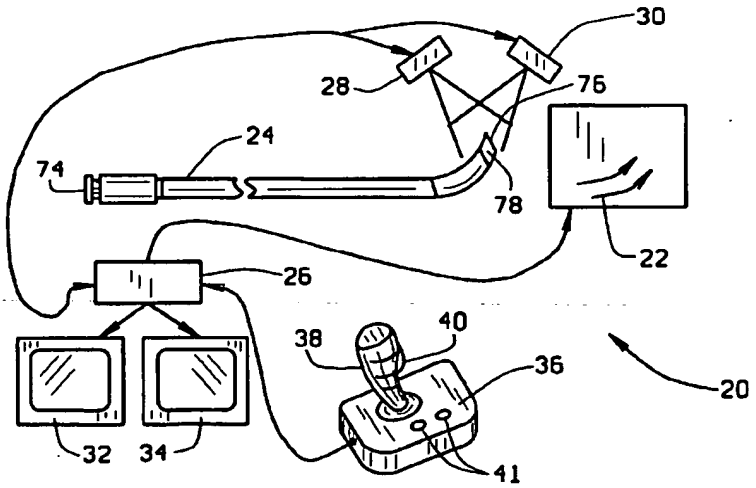
(57) **ABSTRACT**

A method of navigating a magnet-tipped distal end of an elongate medical device through the body includes providing an image display of the part of the body through which the medical device is being navigated and using the display to input the desired path of the medical device by identifying points on the desired path on the display. The magnetic field needed to orient the end of the medical device in the direction of the desired path as indicated on the display is then determined. In one embodiment where only points on the desired path are identified, the field direction is the direction indicated by the points on the desired path. In a second embodiment, where points on the current path and the desired path are identified, the desired angle of deflection is determined, and the direction of the magnetic field is set to lead this desired angle of deflection by 90° to over torque the end of the catheter, and the intensity of the field is determined from a table of experimentally determined field intensities for given angles of deflection.

The apparatus for navigating a magnet-tipped medical device through the body in accordance with the invention includes a magnet system for applying a magnetic field to the magnet-tipped distal end of the medical device to orient the distal end of the medical device; a computer for controlling the magnet system to generate a specified magnetic field in the body part; first and second imaging devices connected to the computer, for providing bi-planar images of the body part through which the medical device is being navigated; first and second displays for displaying the images from the image devices; and an input device for inputting points identifying the desired path of the medical device on each of the displays. The computer is programmed to determine the magnetic field necessary to control orient the medical device on the path input on the displays.

2 Claims, 5 Drawing Sheets



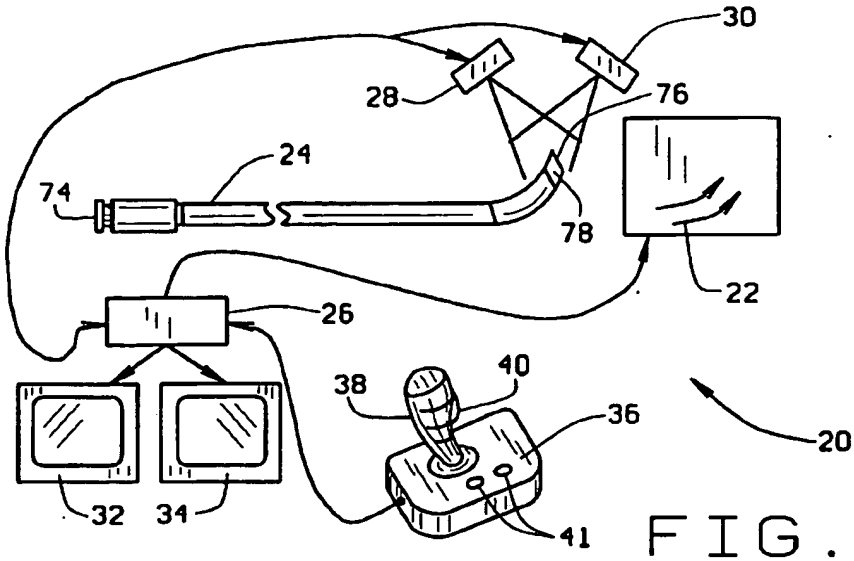


FIG. 1

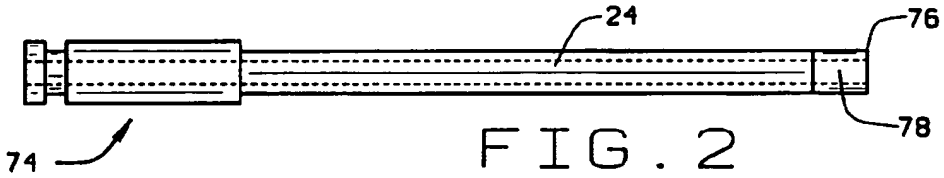


FIG. 2

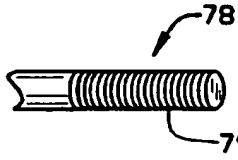


FIG. 3

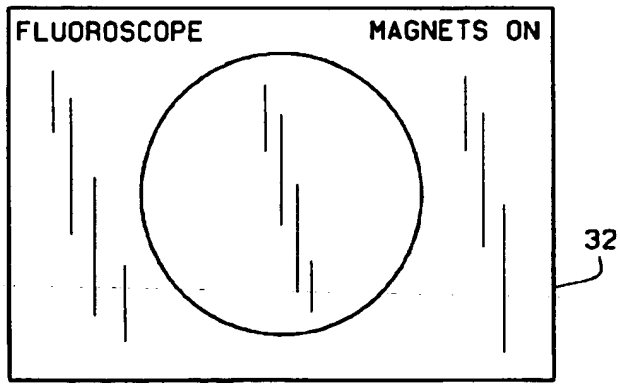


FIG. 4

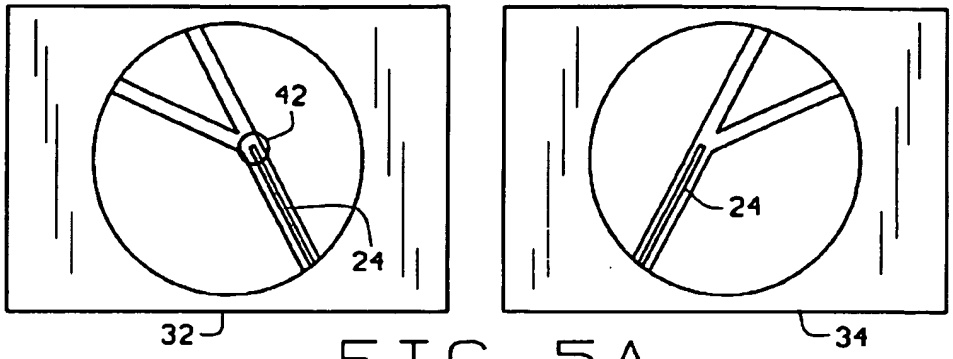


FIG. 5A

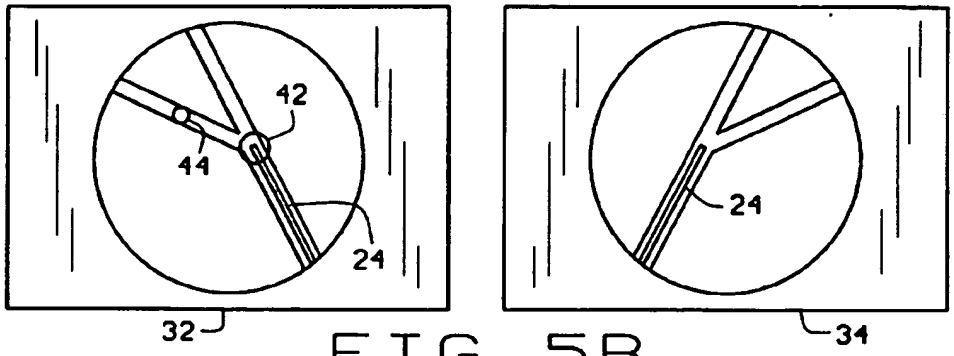


FIG. 5B

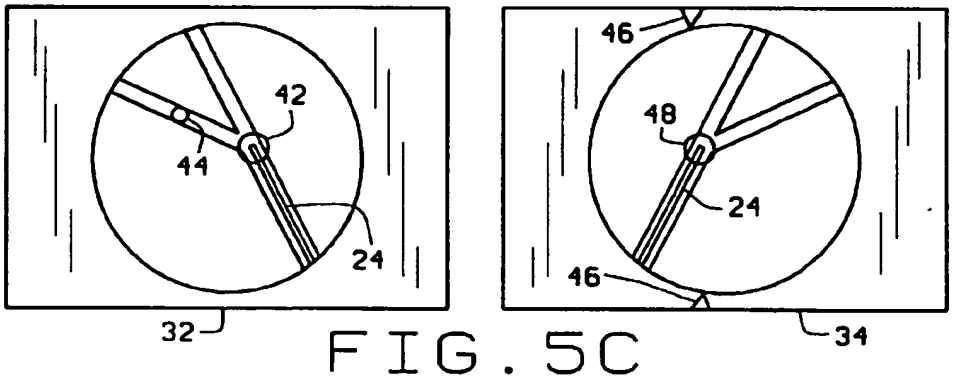


FIG. 5C

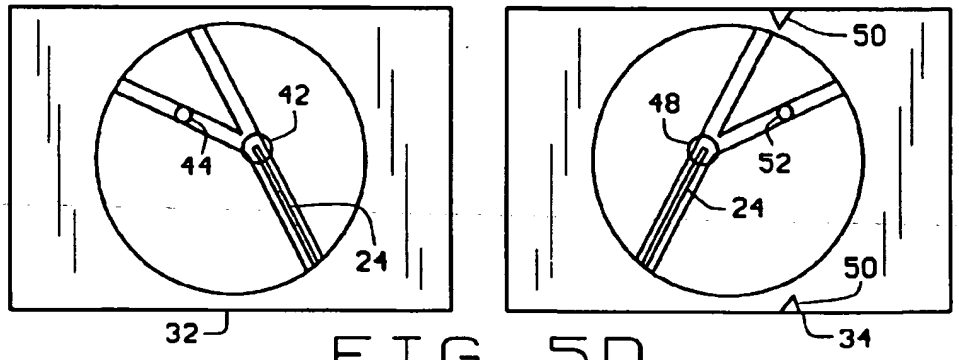


FIG. 5D

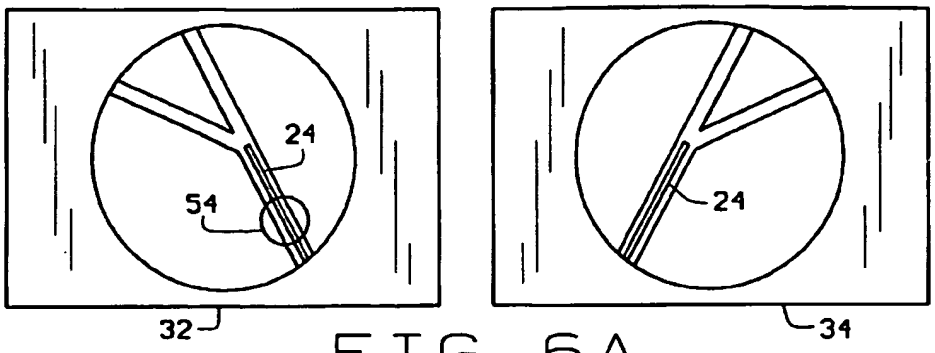


FIG. 6A

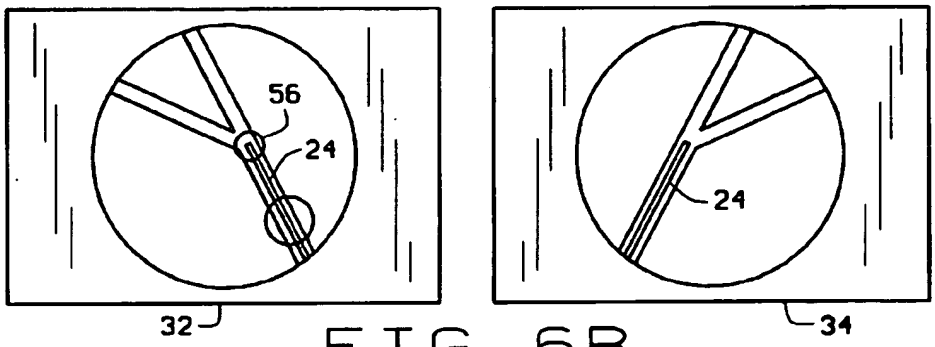


FIG. 6B

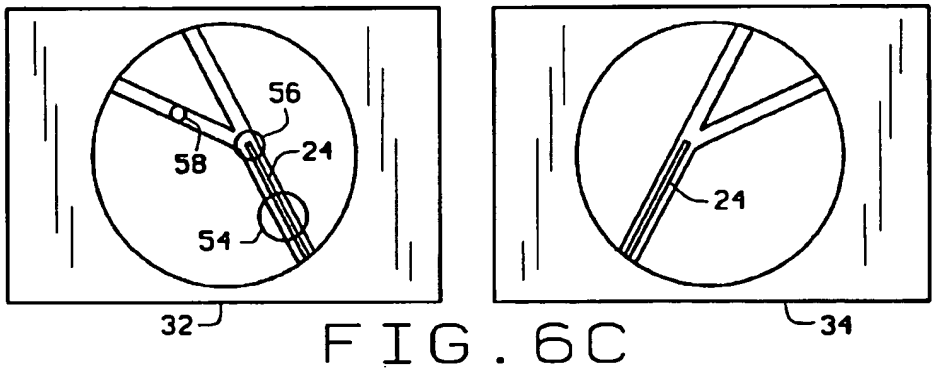


FIG. 6C

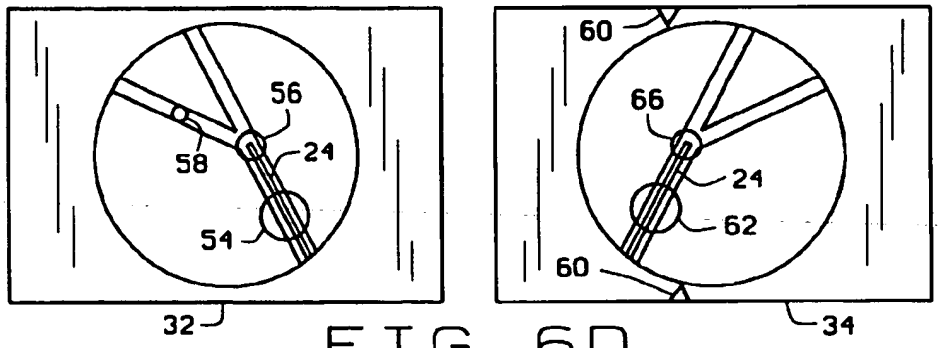


FIG. 6D

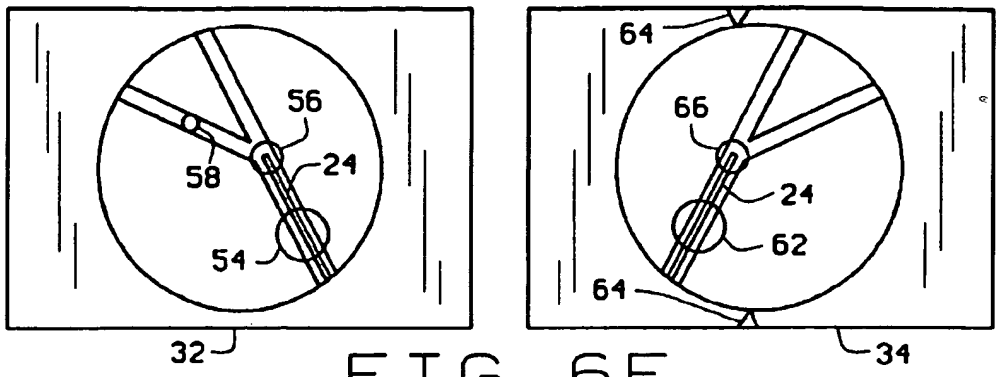


FIG. 6E

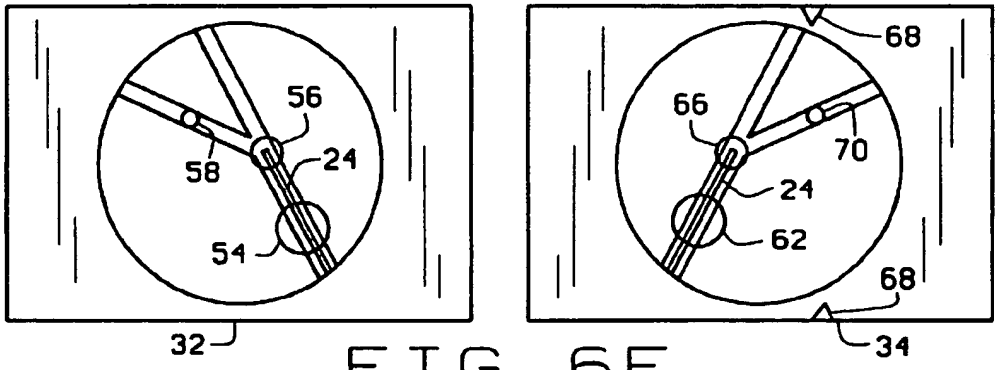


FIG. 6F

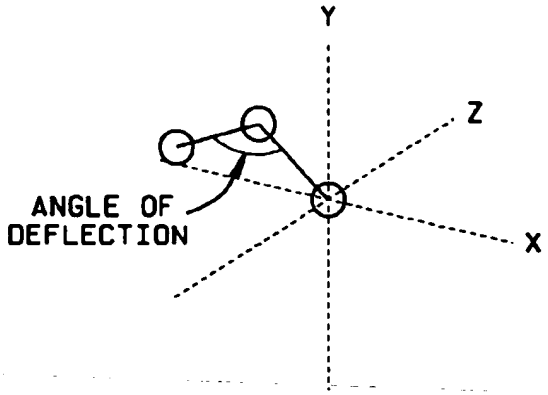


FIG. 7

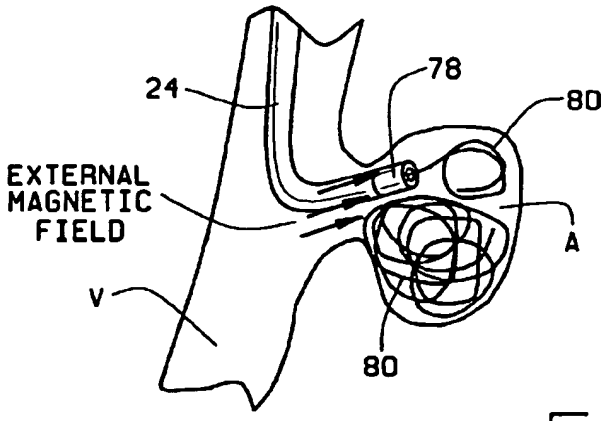


FIG. 8

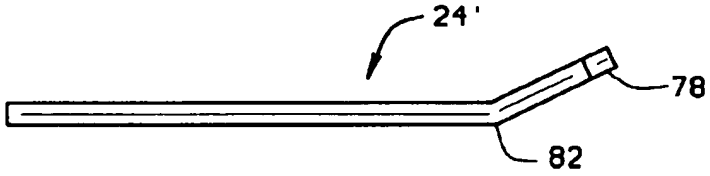


FIG. 9

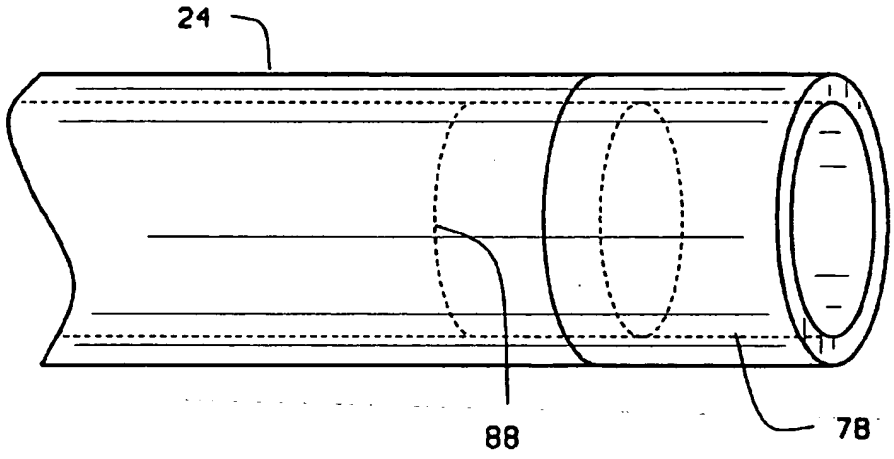


FIG. 10

METHOD AND APPARATUS FOR MAGNETICALLY CONTROLLING CATHETERS IN BODY LUMENS AND CAVITIES

This is a continuation of copending provisional application Serial No. 60/095,710; filed on Aug. 7, 1998.

FIELD OF THE INVENTION

This invention relates to magnetically controlling catheters, and in particular to a method and apparatus for magnetically controlling catheters in body lumens and cavities.

BACKGROUND OF THE INVENTION

It has long been proposed to navigate a magnet-tipped catheter through the body with an externally applied magnetic field. See for example Yodh, A New Magnet System for Intravascular Navigation, Medical and Biological Engineering, Vol. 6, No. 2, March 1968. However, until this invention, the methods of navigating have been too crude and unreliable for serious medical applications. Thus, at the present time the guidance of catheters and other medical devices in body lumens and cavities is still most often accomplished by providing a bent tip on the device or using a guide wire with a bent tip. The physician applies torque and axial push force on the proximal end of the medical device or guidewire to effect tip direction and axial advancement at the distal end. This method of orienting and advancing the tip has several limitations. First, the torque and axial push force is randomly distributed to the distal tip due to the length of the catheter and the tortuousness of the path. Second, the alignment of the catheter in the required direction needs to be synchronized with the advancement of the catheter without changing the catheter orientation. With these two complications, it becomes very difficult to control the distal tip of the catheter from the proximal end. Another method of navigating medical devices through the body is to use blood flow in blood vessels to guide the device through the blood vessels. Although these navigation techniques are effective, they are tedious, require extraordinary skill, and result in long medical procedures that fatigue the user.

SUMMARY OF THE INVENTION

The method and apparatus of the present invention facilitate the navigation of a magnet-tipped medical device through body lumens and cavities. Generally, the method of the present invention comprises: inputting information about the desired path of the medical device; determining the appropriate magnetic field direction and intensity to orient the distal end of the medical device in the direction of the desired path, and applying a magnetic field to the distal end of the medical device to orient the distal end in the direction of desired path. In accordance with this invention, path information is input by providing bi-planar displays of the portion of the body through which the medical device is being navigated. The desired path, and more particularly points along the desired path, is identified on each of the displays. In accordance with a first embodiment of this invention, the user identifies the point where the user desires a direction change (which is usually where the catheter tip is positioned) and a point on the desired new path on each of the displays. The identification of the points on the two bi-planar displays uniquely identifies the points in the three dimensional space inside the body part. The direction of the line or vector including the two points is then determined, and the magnet system is operated to create a magnetic field in the direction of this vector, to orient the distal tip of the catheter.

In accordance with a second embodiment of this invention, the user identifies three points on the two bi-planar displays: a point on the current path of the catheter, the point where the user desires to initiate a direction change, and a point on the desired new path of the catheter. The identification of the points on the two bi-planar displays uniquely identifies the points in the three dimensional space inside the body part. The desired angle of deflection is then determined, and the magnet system is controlled to apply a magnetic field in a direction that provides the maximum over torque (i.e., leads the desired angle of deflection by 90° in the same plane as the desired angle of deflection). The intensity of the magnetic field is determined based upon a table of empirical data which characterizes the required magnetic field strength for a given angle of deflection for a particular medical device.

Generally, the apparatus of the present invention comprises a magnet system for applying a magnetic field to the magnet-tipped distal end of a medical device, to navigate, orient, and hold the distal end of the medical device in the body. The apparatus also includes a computer for controlling the magnet system. First and second imaging devices, connected to the computer, provide images of the body part through which the catheter is being navigated. The computer displays these images on two displays. A controller, connected to the computer, has a joystick and trigger for the user to input points on the displays for two-point and three-point navigation according to the principles of the present invention.

The method and apparatus of the present invention are particularly adapted for use with an elongated medical device such as a catheter, but could be used with a guidewire or other device. In the preferred embodiment, the catheter consists of a distal section that contains a permanent or permeable magnet with an inner hole to allow the passage of fluids and other agents.

The method and apparatus of this invention allow for fast and efficient navigation of magnetic tipped catheters and other medical devices in the body. The method and apparatus provide an easy to use, intuitive interface that allows the user to identify the desired path on an image of the body. The angle of change and the necessary magnetic field to effect that change are automatically determined. The determination of the necessary magnetic field automatically accounts for the lag angle and other physical properties of the catheter. A limit on the angle of deflection can also be imposed to reduce the time necessary for the magnet system to operate, thereby speeding the navigation through the body. These and other features and advantages will be in part apparent, and in part pointed out hereinafter.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic view of an apparatus for navigating a catheter through body lumens and cavities in accordance with the principles of this invention;

FIG. 2 is a top plan view of a magnet-tipped catheter of the type that can be used in the method and with the apparatus of this invention;

FIG. 3 is a perspective view of the distal end of the catheter, provided with a coil spring in accordance with an alternate construction of the present invention;

FIG. 4 is a front elevation view of a possible layout of one of the displays employed in the apparatus of the present invention;

FIGS. 5A–5D are front elevation views of the two displays employed in the apparatus of the present invention, showing the steps for inputting points for the two-point navigation system of the first preferred embodiment;

FIGS. 6A–6F are front elevation views of the two displays employed in the apparatus of the present invention, showing the steps for inputting points for the three-point navigation system of the second preferred embodiment;

FIG. 7 is a perspective view illustrating the determination of the angle of deflection from the present catheter path to the desired catheter path in the second preferred embodiment;

FIG. 8 is a schematic view of how the method and apparatus of the present invention can be used to guide and hold a catheter for the treatment of an aneurysm in a blood vessel;

FIG. 9 is a perspective view of a catheter with a bent distal end portion according to an alternate construction of the present invention; and

FIG. 10 is a perspective view of the distal end of a catheter showing a method of securing a magnet on the distal end.

Corresponding reference numerals indicate corresponding parts throughout the several views of the drawings.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

An apparatus for navigating a medical device through body lumens and cavities constructed in accordance with the principles of this invention is indicated generally as **20** in FIG. **1**. The apparatus **20** includes a magnet system **22** for applying a magnetic field to the magnet-tipped distal end of a medical device such as catheter **24**, to navigate the distal end of the catheter through a portion of the body. While the description of the preferred embodiment references catheter **24**, it is understood that method and apparatus apply to other medical devices having magnetically steerable distal ends, e.g., guidewires, endoscopes, etc. The apparatus **20** also includes a computer **26** for controlling the magnet system **22**. First and second imaging devices **28** and **30**, connected to the computer **26**, provide bi-planar images of the body part through which the catheter **24** is being navigated. The computer **26** displays these images on displays **32** and **34**. The computer **26** also displays interface information on the displays to facilitate inputting information about the desired path. A controller **36**, connected to the computer **26**, has a joystick **38** and trigger or button **40** for the user to operate the apparatus **20**. The magnet system **22** is preferably a set of electromagnetic coils that can be disposed around the body part to create a magnetic field within the body part of variable direction and intensity. A suitable magnet system **22** is that disclosed in U.S. Pat. No. 4,869,247, issued Sep. 26, 1989, entitled Video Tumor Fighting System and U.S. Pat. No. 5,125,888, issued on Jun. 30, 1992, entitled Magnetic Stereotactic System for Treatment Delivery, the disclosures of which are incorporated herein by reference.

The computer **26** preferably includes an image processing module programmed to input the x-ray images from the imaging devices **28** and **30**, and overlaying the text of the system's status and displaying the current position of the joystick controller **36** (i.e., the cursor). The computer **26** provides standard capabilities that would be utilized in a typical x-ray imaging suite. Those features include bi-planar fluoroscope, background images, roadmaps, fluoroscope over roadmaps, roadmap acquisition review, image storing, in addition to other features. To direct the catheter **24**, the user first enables the fluoroscope mode to position the catheter. A bi-planar background image is then captured. While injecting x-ray opaque contrast dye, a bi-planar roadmap image is stored. Using the joystick **38**, the physician indicates the direction to orient the catheter. This is accomplished by selecting several points on each of the x-ray images. A wide variety of suitable computer systems and image processors are available. The inventors have implemented the apparatus with a Motorola VME processor, a Datacube MV-200 Image Processing Module, and a Matrix Daadio Multi-function I/O Module.

The imaging devices **28** and **30** are preferably x-ray fluoroscopes that provide real-time images of the body part through which the catheter **24** is being navigated. The imaging devices **28** and **30** are arranged so that each provides an image of the same portion of the body part, but at different orientations or planes. The imaging devices **28** and **30** are preferably oriented at right angles to each other so that their respective images are in perpendicular planes, but this is not essential. When perpendicular, the imaging device **28** provides a view in the X-Z plane and the imaging device **30** provides a view in the Y-Z plane. The imaging devices **28** and **30** are connected to the computer **26**, which processes the image signals and displays the processed images on displays **32** and **34**. The displays **32** and **34** show the internal structure of the body part through which the catheter **24** is being navigated, as well as the present location of the catheter in the body part. As shown in FIG. **4**, the images are displayed on the screen of the displays **32** and **34**. The displays **32** and **34** can also provide other status information about the system **20**, for example, the status of the magnet system **22**. In the preferred embodiment, there are two separate displays **32** and **34**, each on a separate display device. However, it should be understood that both displays **32** and **34** could be displayed juxtaposed on a single display device, or the displays **32** and **34** could be displayed alternately on a single display device.

Although in the preferred embodiment two imaging devices are used, other imaging techniques, for example CT or MRI imaging can be used, which can provide a three dimensional image of the body part with just one imaging device. In such a case, a single imaging device may be used instead of two imaging devices. Furthermore, while in the preferred embodiment two displays **32** and **34** are used, it may be possible through image processing or through the use of three-dimensional imaging techniques such as CT or MRI imaging, to show the body part in three dimensions in a single display. In this case, the desired catheter path or points on the desired catheter path can be identified on the single display without departing from the principles of this invention.

The computer **26** also provides an interface for the user to control the magnet system **22** through the displays **32** and **34**. The user identifies the desired path for the catheter **24** on each of the displays **32** and **34**. This is conveniently done with the joystick controller **36**, which can manipulate markers that the computer **26** overlays on the displays **32** and **34** to identify points on the desired path of the catheter **24** for providing input information to the computer **26** for controlling the magnet system **22**.

According to a first embodiment of this invention, the user identifies the desired path of the distal tip of the catheter **24** on each the displays **32** and **34** by identifying a point on the display where the user desires to change the direction of the catheter (typically where the catheter tip is positioned) and a point on the desired new path of the distal tip of the catheter. From the identification of these points, the desired three dimensional orientation of the distal end of the catheter

is determined. Once the desired orientation is determined, the magnet system **22** applies a magnetic field of the orientation and strength-specified. According to a second embodiment of this invention, the user identifies the current path and the desired path of the distal tip of the catheter on each of the displays by identifying a point on the current path of the distal tip of the catheter, a point where the user desires to change the direction of the catheter, and a point on the desired new path of the distal tip of the catheter. From the identification of these points, the desired angle of deflection is determined. Once the desired angle of deflection is determined, the appropriate orientation and field intensity of the magnetic field are determined. In the second preferred embodiment, the orientation of the magnetic field leads the desired angle of deflection by 90° so that the magnetic field applies a maximum over torque to the distal tip of the catheter. The intensity of the magnetic field is determined from an empirically determined table of field intensities required to achieve a desired deflection angle, for the particular catheter **24**.

The output of the x-ray/fluoroscopes **28** and **30** are connected to the computer **26** with an image processing module. The image processing module is programmed to input the x-ray images, apply overlay text of the system status, and to indicate the current position of the joystick controller (the cursor). The user uses the joystick **38** of the joystick controller **36** to select positions on the x-ray images on the displays **32** and **34** to indicate the desired orientation of the catheter **24**. After selecting the orientation of the catheter, a button is pressed on the joystick controller **36** to initiate computer control of the magnet system **22**. The computer **26** computes the required external magnetic field strength and/or direction to orient the catheter **24** as indicated on the displays **32** and **34**. From this calculation, the computer **26** determines the power settings of each of the magnet coils within the magnet system **22**. The computer **26** then programs digital-to-analog output modules to the determined settings to control each of the magnet power supplies in the magnet system **22**. The composite field generated by each of the magnets within the magnet system **22** is equivalent to the predetermined field direction and strength for the current catheter tip location.

The computer **26** provides a convenient user interface to facilitate the input of orientation information via the displays **32** and **34**. More specifically, in the two point navigation system of the first preferred embodiment of the present invention, the user identifies the point where the user desires to change the direction of the catheter by manipulating a marker over this point on one of the displays with the joystick **38** of controller **36**, and locking the marker in place by pressing one of the buttons **40** on the joystick controller. The user then identifies a point on the desired new path of the catheter **24** in the same manner, using the joystick **38** of controller **36** to manipulate a marker over this point on the display, and locking the marker in place by pressing one of the buttons **40** on the joystick controller. After these two points have been identified on the display, the user then switches to the other display and identifies the two points on the other display in the same manner, using the joystick **38** of the joystick controller **36** to manipulate markers over the points, and locking the markers in place by pressing one of the buttons **40** on the joystick controller. Indicia appear on the second display to indicate the line along which the points identified on the first display lie, to facilitate the identification of the points on the second display.

Additional controls can be provided, for example buttons **41** on controller **36**, to refine the direction control of the medical device. For example, in the two-point navigation system of the first preferred embodiment, the buttons **41** could increase and decrease the field strength. Increasing the field strength causes the distal end of the catheter to more closely conform to the magnetic field direction, decreasing the lag angle, and decreasing the field strength increases the lag angle. In the three-point navigation system, the buttons **41** could increase or decrease the field strength and/or change the direction of the magnetic field, to increase and decrease the angle of deflection. These controls allow fine adjustment of the catheter orientation without the need to reposition the catheter tip using the two-point or three-point navigation system.

The identification process in the two-point navigation system of the first preferred embodiment is shown in FIGS. **5A–5D**. In FIG. **5A**, the user uses joystick **38** on the joystick controller **36** to manipulate marker **42** on display **32** over the point where the user wants to change the direction of the catheter and presses button **40** to lock the marker in place. In FIG. **5B**, the user then uses the joystick **38** on the joystick controller **36** to manipulate marker **44** on the display **32** over a point on the desired new path of the catheter, and presses button **40** to lock the marker in place. Once these two points have been identified, the user switches to display **34**. In the preferred embodiment this is done by using the joystick **38** to manipulate a cursor on the display **32** to the display, adjacent to display **34**, to cause the cursor to switch to the display **34**. As shown in FIG. **5C**, indicators **46** appear at the top and bottom of the display **34** to indicate the line along which the marker **42** on display **32** lies, to help the user identify the same point on display **34**. The user then uses the joystick **38** on the joystick controller **36** to manipulate marker **48** over the corresponding point on display **34** where the user wants to change the direction of the catheter. When the marker **48** is properly positioned, the user locks the marker in position by pressing a button **40** on the joystick controller **36**. As shown in FIG. **5D**, indicators **50** then appear at the top and bottom of the display to indicate the line along which marker **44** on screen **32** lies, to help the user identify the same point on display **34**. The user uses the joystick **38** on the joystick controller **36** to position marker **52** on a point on the desired new path of the catheter, and locks the marker by pressing a button **40** on the joystick controller.

The markers **42** and **48** on screens **32** and **34**, respectively, identify the point where the user desires to change the direction of the catheter, and preferably have similar size and shape to indicate to the user that they identify the same point. In the first preferred embodiment markers **42** and **48** are medium circles, but could, of course, have some other size, shape, and appearance. Similarly, the markers **44** and **52** on screens **32** and **34**, respectively, identify a point on the desired new path of the catheter, and preferably have similar sizes and shapes to indicate to the user that they identify the same point. In the first preferred embodiment markers **44** and **52** are small circles, but could, of course, have some other size, shape, and appearance.

The markers **42** and **48** and **44** and **52** identify unique points in three dimensional space in the body part. The computer **26** determines the direction of the line between these two points, and cause the magnet system **22** to generate a magnetic field in the same direction, which causes the magnet on the distal end of the catheter **24** to align the distal end of the catheter in the same direction. The intensity of the magnetic field is preset or selected by the user balancing the need for magnetic field strength versus the need for efficiency.

The identification process in the three-point navigation system of the second preferred embodiment is shown in FIGS. 6A–6F. In FIG. 6A, the user uses joystick 38 on the joystick controller 36 to manipulate marker 54 on display 32 over a point on the current path of the catheter 24, and presses button 40 to lock the marker in place. As shown in FIG. 6B, a second marker 56 appears, and the user uses the joystick 38 to position this marker over the point where the user desires to change the direction of the catheter 24, and presses button 40 to lock the marker in position. As shown in FIG. 6C, a third marker 58 appears, and the user uses joystick 38 to position this marker over a point on the desired new path of the catheter 24, and presses button 40 to lock the marker in position. The user then switches to the second display 34. In the preferred embodiment this is done by using the joystick 38 to manipulate the cursor on the display to the side of the display 32 adjacent the display 34, which causes the cursor to switch to display 34. As shown in FIG. 6D, indicators 60 appear at the top and bottom of the display 34 to identify the line along which the marker 54 on display 32 lies, and the user uses the joystick 38 to manipulate marker 62 to the corresponding point on the display 34, and presses button 40 to lock the marker in position. As shown in FIG. 6E, indicators 64 appear at the top and the bottom of the display 34 to identify the line along which marker 56 on display 32 lies, and the user uses the joystick 38 to manipulate marker 66 to the corresponding point on display 34, and presses button 40 to lock the marker in position. As shown in FIG. 6F, indicators 68 appear at the top and the bottom of the display 34 to identify the line along which marker 58 on display 32 lies, and the user uses the joystick 38 to manipulate marker 70 to the corresponding point on display 34, and presses button 40 to lock the marker.

The markers 54 and 62, 56 and 66, and 58 and 70 each define a unique point in the three dimensional space in the body part. The computer 26 calculates the angle formed by these three points, which is the desired angle of deflection, and then controls the magnet system 22 to apply a magnetic field of sufficient direction and intensity to cause the distal tip of the catheter to bend at this angle. In the preferred embodiment the computer 26 controls the magnets to apply a magnetic field at a 90° over-torque, i.e., it leads the desired angle of deflection by 90°, in the same plane as the desired angle of deflection. This application of force normal to the desired orientation of the catheter 24 applies the maximum torque on the distal end of the catheter, and thus allows the minimum field intensity to be used. By applying a 90° over torque to the catheter tip, the magnetic field strength can be minimized while still achieving the desired angle of deflection. Reducing the magnetic field strength reduces the time it takes to apply the field. The strength of the applied magnetic field is preferably determined based on the properties (primarily the lag angle) of the catheter 24. In this second preferred embodiment, the intensity of the field required to achieve a desired angle of deflection with the application of a 90° over-torque is determined for a plurality of angles through experiment with a catheter of a given stiffness. For example the required field intensity is determined for the angles at 15° increments, i.e., for 15°, 30°, 45°, 60°, 75°, 90°, 105°, 120°, 135°, 150°, and 165°. Where the applied field is nearly axial, the bending of the distal end of the catheter 24 is unreliable. In such cases, the direction of the magnetic field is either limited to a predetermined maximum such as 170°, or the computer orients the catheter in two steps, first causing the magnet system 22 to apply a magnetic field of a first direction at a first intensity, and then causing the magnet system to apply a magnetic field of a second direction at a second intensity. The computer 26 uses the stored table of data and the desired angle of deflection to determine the intensity, interpolating for desired deflection angles that fall between the increments in the table.

The markers 54 and 62 on displays 32 and 34, respectively, identify a point on the current path of the catheter 24, and preferably have similar size and shape to indicate to the user that they identify the same point. In the second preferred embodiment markers 54 and 62 are large circles, but could, of course, have some other size, shape, and appearance. The markers 56 and 66 on displays 32 and 34, respectively, identify the point where the user desires to change the direction, and preferably have similar size and shape to indicate to the user that they identify the same point. In the second preferred embodiment markers 56 and 66 are medium circles, but could, of course, have some other size, shape, and appearance. Similarly, the markers 58 and 70 on screens 32 and 34, respectively, identify a point on the desired new path of the catheter, and preferably have similar sizes and shapes to indicate to the user that they identify the same point. In the second preferred embodiment markers 58 and 70 are small circles, but could, of course, have some other size, shape, and appearance.

The amount of time required to change the direction of the applied magnetic field is dependent on the field strength required to deflect the catheter 24 at a particular angle. Generally, the larger the deflection angle required, the stronger the magnetic field required. Thus, the magnitude of the field strength can be limited to a predetermined maximum, to minimize the delay during navigation, by preselecting a maximum catheter deflection angle. The user can select any deflection angle, but the actual angle would be limited to a preset maximum. While limiting the change to a predetermined maximum angle, the catheter can still be navigated successfully through the body, and the delay between magnetic field changes can be minimized. Thus, it is possible to preset the maximum angle of change, to for example 45° or some other suitable angle. In this example, all angles requested by the user would be reduced to 45°.

In the first preferred embodiment, the computer 26 is programmed to reconstruct the data for each of the points (the X-Z data input from display 32 and the Y-Z data input from display 34) into a point in three dimensional space. The computer 26 then determines the vector between the first point (identified by markers 42 and 48) and the second point (identified by markers 44 and 52), and controls the magnet system 22 to create a magnetic field within the body part in the same direction as the vector. Such a method of controlling the motion direction is disclosed in co-pending U.S. patent application Ser. No. 08-920,446, filed Aug. 29, 1997, entitled Method and Apparatus for Magnetically Controlling Motion Direction of a Mechanically Pushed Catheter. The strength of the magnetic field can be predetermined by the system or selected by the user, balancing the accuracy of the positioning of the catheter against the increased coil ramp time required for greater field strength.

In the second preferred embodiment, the computer 26 is programmed to reconstruct the data for each of the points (the X-Z data input from display 32 and the Y-Z data input from display 34) into a point in three dimensional space. The computer 26 then determines the vector between the first point (identified by markers 54 and 62) and the second point (identified by markers 56 and 66) and the vector between the second point and the third point (identified by markers 58 and 70), and the angle between these vectors, which equals the desired angle of deflection. The computer 26 adds 90° to

the desired angle of deflection (in the same plane as the desired angle of deflection) to over torque the distal end of the catheter. The computer **26** automatically limits the angle of the magnetic field to less than a predetermined angle, preferably 170°. The computer **26** then determines the appropriate magnetic field intensity in a look-up table of empirically collected field intensities to achieve desired angle of deflections with a 90° over torque. The computer **26** linearly interpolates for angles of deflection between those in the look-up table.

The computer **26** then controls the magnet system **22** to establish a magnetic field in the body part with the determined field direction and field intensity.

The catheter is then manually advanced. Following advancement, the magnet system **22** is disabled to remove the external magnetic field. Alternatively, the physician could utilize the system to hold the catheter during treatment or pull the catheter.

A catheter **24** adapted for use with the navigation method and apparatus of the present invention is shown in FIGS. **2** and **3**. The catheter **24** has a proximal end **74** and a distal end **76**. There is preferably at least one magnet **78** in the distal end of the catheter. This magnet **78** may either be a permanent magnet or a permeable magnet. The magnet **78** is of sufficient size to cause the distal end portion of the catheter to align with an applied magnetic field. The catheter **24** tends to resist this alignment because of stiffness of the material and other physical properties, and this resistance is manifested in a "lag angle" between the direction of the applied magnetic field at a given intensity, and the direction of the distal end of the catheter. In accordance with the principles of this invention, this lag angle is characterized, either as a formula or in a look-up table, so that it can be taken into account in determining the magnetic field intensity to apply to control the distal end of the catheter.

The magnet **78** preferably has an annular shape and is secured at the distal end of the catheter, for example by embedding the magnet in the wall of the catheter, or attaching it to the end of the wall of the catheter, for example with adhesive. In an alternative construction, a plurality of spaced magnets can be provided in the distal end of the catheter. In the embodiment shown in FIG. **3**, the magnet **78** is a coil **79** of magnetically permeable material embedded in the distal end portion of the wall of the catheter, which can be oriented in a magnetic field. In the embodiment shown in FIG. **10**, a sleeve **88**, which could be made from stainless steel or titanium, is disposed in the distal end of the catheter, and projects from the distal end, and an annular magnet **78** fits over the sleeve **88** and is secured, for example, with adhesive.

An alternative construction of the catheter **24'** is shown in FIG. **9**. Catheter **24'** is similar in construction to catheter **24** except that the distal end portion of catheter **24'** has a bend **82** formed therein. The catheter **24'** works with the method and apparatus of the present invention. The application of a magnetic field causes the catheter **24'** to rotate about its axis so that the bend faces the desired direction. The bend thus reduces the field strength that must be applied to orient the distal end of the catheter **24'**. This reduces the amount of time required by the magnet system **22** and speeds navigation.

OPERATION

An application of the navigation method and apparatus of the present invention is illustrated in FIG. **8**, where, as part of an interventional neuroradiology procedure, platinum coils **80** are inserted into an aneurysm to occlude the aneurysm. In the past problems have occurred due to randomness in the placement of the coils. The location where a coil **80** ends up depends upon the position of the tip of the catheter **24**. In FIG. **8**, catheter **24** has been navigated through blood vessel V, to the site of an aneurysm A. The two-point or three-point navigation system for inputting the desired orientation of the end of the catheter **24** can be used to accurately orient the end of the catheter so that the catheter can be advanced into the aneurysm A, to deliver coils **80** or other therapeutic agents to the aneurysm A. The two-point or three point navigation of the present invention allows more precise control of the position of the distal end of the catheter **24**, to better distribute the coils **80** in the aneurysm A.

What is claimed is:

1. A method of navigating a magnet-tipped distal end of an elongate medical device through the body, the method comprising the steps of:

providing bi-planar image displays of the body part through which the catheter is being navigated;

inputting points on a desired path for the medical device in three dimensions by identifying each point on the two bi-planar displays of the body part, including a first point on the current path of the medical device, a second point where the user desires to change the direction of the medical device, and a third point on the desired new path for the medical device;

determining the direction of a magnetic field capable of orienting the distal end of the medical device to correspond with the direction of the desired path between the second point and the third point, by determining the desired angle of deflection by determining the angle between a line between the first and second points and a line between the second and third points, and determining the direction of a magnetic field to achieve the desired angle of deflection and adding 90° to the desired angle of deflection;

applying the determined magnetic field to the distal end of the medical device to orient the distal end of the device in the direction of the desired path; and

advancing the medical device to move the distal end of the device in the direction in which it is oriented by the magnetic field.

2. The method according to claim **1** wherein the maximum angle of the applied field is less than about 170°.

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